

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

FRESENIUS MEDICAL CARE
HOLDINGS, INC., et al.,

No. C 03-1431 SBA

Plaintiffs,

ORDER

v.

[Docket No. 441]

BAXTER INTERNATIONAL, INC., et al.,

Defendants.

This matter comes before the Court on Plaintiffs Fresenius Medical Care Holdings, Inc. and Fresenius USA, Inc.'s (collectively, "Plaintiffs" or "Fresenius") Motion for Summary Judgment of Invalidity of the Asserted Claims of U.S. Patent Nos. 5,326,476 and 5,744,027. The Court has read and considered the arguments presented by the parties in the papers submitted to the Court as well as the arguments set forth on the record at the May 16, 2006 hearing. The Court hereby DENIES Fresenius' Motion for Summary Judgment of Invalidity of the Asserted Claims of U.S. Patent Nos. 5,326,476 and 5,744,027.

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BACKGROUND**A. Procedural Background**

Plaintiffs and counter-defendants Fresenius USA, Inc.¹ and Fresenius Medical Care Holdings, Inc. (collectively "Fresenius") initiated this suit on April 4, 2003 by filing a Complaint for Declaratory Judgment of Non-infringement and Invalidity against defendants and counter-plaintiffs Baxter International, Inc. and Baxter Healthcare Corporation (collectively "Baxter").² Fresenius cited five patents in its complaint: (1) U.S. Patent No. 5,247,434 (the "'434 Patent")³; (2) U.S. Patent No. 5,326,476 (the "'476 Patent")⁴; (3) U.S. Patent No. 6,284,131 B1 (the "'131 Patent")⁵; (4) U.S. Patent No. 5,486,286 (the "'286 Patent")⁶; and (5) U.S. Patent No. 5,744,027 (the "'027 Patent")⁷ (collectively "patents-in-suit").

Baxter is the assignee and record owner of the patents-in-suit. Baxter has commercialized the inventions of the patents-in-suit through hemodialysis instruments, such as the "System 1000." Amend. Ans. at ¶ 19. On May 14, 2003, Baxter answered and counterclaimed that Fresenius' 2008H and/or 2008K hemodialysis machines infringe four of the five patents.

On October 9, 2003, pursuant to this Court's Patent Local Rules, Baxter served its Preliminary

¹Fresenius Medical Care Holdings, Inc. is the country's leading full service provider of dialysis care. Compl. at ¶ 4. Through various affiliates, the company treats approximately 79,600 patients in approximately 1,080 dialysis clinics throughout the United States. *Id.* Fresenius USA, Inc. is a wholly owned subsidiary of Fresenius Medical Care Holdings, Inc. and has a research and manufacturing facility in Walnut Creek, California. *Id.*

²Baxter Healthcare Corporation and Baxter International Inc. are affiliated corporations that make dialysis machines, equipment, and supplies, which are sold to dialysis clinics. Compl. at ¶ 5.

³The '434 Patent was issued on September 21, 1993 and claims an invention entitled "Method and Apparatus for Kidney Dialysis." Amend. Ans. at ¶ 17.

⁴The '476 Patent was issued on July 5, 1994 and claims an invention entitled "Method and Apparatus for Kidney Dialysis Using Machine with Programmable Memory." Amend. Ans. at ¶ 26.

⁵The '131 Patent was issued on September 1, 2001 and claims an invention entitled "Method and Apparatus for Kidney Dialysis." Amend. Ans. at ¶ 35.

⁶The '027 Patent was issued on April 28, 1998 and claims an invention entitled "Apparatus for Kidney Dialysis." Amend. Ans. at ¶ 46.

⁷The '286 Patent was issued on April 28, 1998 and claims an invention entitled "Apparatus for Performing a Self-Test of Kidney Dialysis Membrane." Amend. Ans. at ¶ 55.

1 Infringement Contentions.

2 On October 20, 2003, Baxter amended its Answer and Counterclaims to assert infringement of
3 the '286 Patent.

4 On November 24, 2003, pursuant to Patent Local Rule 3-3, Fresenius served its Preliminary
5 Invalidity Contentions. After Fresenius filed a Motion to Compel Further Disclosures on December 22,
6 2003, Baxter served supplemental infringement contentions.

7 On October 14, 2004, a claim construction hearing was held on certain disputed terms. After
8 the Court issued its claim construction ruling on November 22, 2004, the parties met and conferred in
9 order to narrow the selection of additional terms to be construed by the Court.

10 On December 28, 2004, Baxter served its Final Infringement Contentions pursuant to Local Rule
11 3-6(a).

12 On January 5, 2005, Baxter filed a Motion for Partial Summary Judgment of Infringement with
13 respect to claim 1 of the '131 Patent and claim 26 of the '434 Patent.

14 On January 6, 2005, the parties requested that the Court construe one additional claim term from
15 claim 26(a) of the '434 Patent: "means for controlling a dialysate parameter selected from a group
16 consisting of dialysate temperature and dialysate concentration."

17 On January 18, 2005, Fresenius served its Final Invalidity Contentions pursuant to Patent Local
18 Rule 3-6(b). In its Final Invalidity Contentions, Fresenius identified the Sarns 9000, including its
19 operation manuals, as invalidating prior art.

20 On February 15, 2005, Fresenius filed a Cross-Motion for Summary Judgment with respect to
21 whether Fresenius infringed claim 1 of the '131 Patent and claim 26 of the '434 Patent. Also on
22 February 15, 2005, Baxter filed a Motion to Strike Fresenius' Final Invalidity Contentions.

23 On March 1, 2005, this Court issued an order construing the remaining disputed claim term in
24 claim 26(a) of the '434 patent.

25 On August 24, 2005, the Court issued an Order denying Baxter's Motion to Strike Fresenius'
26 Final Invalidity Contentions.

27 On September 2, 2005, this Court issued an Order granting in part and denying in part Baxter's
28 Motion for Partial Summary Judgment and granting and denying in part Fresenius' Cross-Motion for

Summary Judgment. The Court held that Fresenius' 2008K hemodialysis machine infringed claim 26 of the '434 Patent and claim 1 of the '131 Patent. The Court also held that the SVS, Kt/V and Blood Pressure screens of the 2008K did not infringe claim 1 of the '131 Patent.

On February 21, 2006, Fresenius filed the instant Motion for Summary Judgment of Invalidity of the Asserted Claims of U.S. Patent Nos. 5,247,434 and 6,284,131, seeking partial summary judgment that: (1) the asserted claims of the '434 and '131 Patents are invalid as obvious under U.S.C. § 103(a); (2) the asserted claims of the '131 Patent are invalid as anticipated under 35 U.S.C. § 102(b) by the Sarns Manual; and (3) the touch screen claims⁸ of the patents-in-suit are invalid for failure to satisfy the enablement and best mode requirements of 35 U.S.C. § 112. With respect to its obviousness defense, Fresenius requests that the Court enter summary judgment in its favor on the grounds that the '434 and '131 Patents are rendered obvious by the following prior art references: (1) the Sarns Manual; (2) U.S. Patent No. 4,756,706 issued to Kerns (referred to herein as "Kerns" or the "Kerns patent"); (3) U.S. Patent No. 4,898,578 issued to Rubalcaba (referred to herein as "Rubalcaba" or the "Rubalcaba patent"); and (4) U.S. Patent No. 4,370,983 issued to Lichtenstein (referred to herein as "Lichtenstein" or the "Lichtenstein patent").

Also on February 21, 2006, Fresenius filed the instant Motion for Summary Judgment seeking partial summary judgment that: (1) claim 5 of the '476 Patent and claim 11 of the '027 Patent are invalid as obvious under 35 U.S.C. § 103(a); (2) claim 7 of the '476 Patent and claims 1, 2, 4, 6-8, 10, and 12-16 of the '027 Patent are invalid as anticipated under 35 U.S.C. § 102(b); and (3) claim 5 of the '476 Patent is invalid for failure to satisfy the definiteness and enablement requirements of 35 U.S.C. § 112.

On March 7, 2006, Baxter filed a Motion for Partial Summary Judgment of Validity, seeking summary judgment in its favor that the asserted claims of the '434 and '131 Patents are not invalid under 35 U.S.C. § 102 for anticipation, and that certain asserted claims of the patents-in-suit are not invalid under 35 U.S.C. § 112 based on best mode and enablement violations.

Also on March 7, 2006, Baxter filed the following motions: (1) a Motion to Bar Fresenius' Proffered Damages Expert Professor Rubinfeld; (2) a Motion to Strike Fresenius' Best Mode and

⁸The asserted "touch screen" claims are claims 26-31 of the '434 Patent, claims 1-3 and 13-16 of the '131 Patent, claim 5 of the '476 Patent, and claim 11 of the '027 Patent.

Anticipation Defenses, in Part, Under Local Rule 3-7; and (3) a Motion to Bar the Expert Testimony of Jeff Riley.

On March 14, 2006, pursuant to a stipulation between the parties, the Court issued an Order dismissing with prejudice: (1) all claims, counterclaims, and defenses of the parties concerning the '286 Patent and claims 1 and 6 of the '476 Patent; (2) all claims, counterclaims, and defenses of the parties concerning Fresenius' model 2008H hemodialysis machine; (3) Fresenius' affirmative defenses of laches, estoppel, failure to mark, and prosecution laches with respect to all of the patents-in-suit; (4) Fresenius' affirmative defense of unenforceability with respect to the '286 Patent and the '027 Patent; (5) Fresenius' defense of improper inventorship based on alleged contribution by Ziba Design with respect to all of the patents-in-suit; (6) Fresenius' defense of indefiniteness as to claims 1, 13 and 14 of the '131 Patent.

On March 21, 2006, Fresenius filed its Opposition to Baxter's Motion for Partial Summary Judgment of Validity, attaching in support several declarations, including a declaration from Richard Alan Griewski. Also on March 21, 2006, Baxter filed the following motions: (1) a Motion to Strike the Declaration of Charles Ragsdale; (2) a Motion to Strike PTO Documents as Exhibits to Fresenius' Motion for Summary Judgment of Invalidity of '434 and '131 Patents; and (3) a Motion to Strike Exhibits 1 and 13 to Fresenius' Motion for Summary Judgment of Invalidity of '476 and '026 Patents.

On March 28, 2006, Baxter also filed a Motion to Strike the Declaration of Richard Alan Griewski.

B. Factual Background

1. Hemodialysis

Dialysis is a process in which solutes transfer from one fluid compartment to another across a semipermeable⁹ membrane. Ward Decl. at ¶ 10. In hemodialysis, the semipermeable membrane is contained in a device known as a dialyzer and the two fluid compartments are the blood and the dialysate, a man-made solution containing the major ionic constituents of blood. *Id.* To perform hemodialysis, a patient's blood is taken from the bloodstream and circulated through the dialyzer – which is sometimes referred to as an artificial kidney – where it undergoes purification. *Id.* The urea

⁹A semipermeable membrane is one which allows free passage of small solutes, but which is impermeable to large solutes. *Id.*

1 and other waste metabolites are removed through a process known as diffusion. *Id.* at ¶ 11. The
2 purified blood is then returned to the patient's blood stream and the dialysate, containing the waste
3 products, is discarded. *Id.* at ¶ 10.

4 Another principal function of hemodialysis is to remove the fluid consumed by the patient
5 between dialysis treatments. *Id.* at ¶ 12. Fluid is removed by creating a pressure difference between
6 the blood and dialysate sides of the dialyzer membrane so that fluid flows from the blood to the
7 dialysate. *Id.* The rate of fluid flow depends on the pressure difference and the water permeability of
8 the dialyzer membrane. *Id.*

9 In the beginning of the 1980's, hemodialysis machines consisted of simple electro-mechanical
10 systems and changes in operating parameters during the course of treatment required an action by the
11 operator. *Id.* at ¶ 16. However, when it was realized that some of the adverse symptoms patients
12 experienced during dialysis could be ameliorated by varying the operating parameters during dialysis,
13 hemodialysis machines began to incorporate microprocessor-based ultrafiltration control systems. *Id.*
14 at ¶¶ 14, 16. Microprocessor-based control systems control the dialysate compartment pressure to
15 achieve the desired ultrafiltration rate. *Id.* at ¶ 16. Microprocessor systems have the benefit of allowing
16 many of the previously manual safety monitoring and alarm operations, such as pre-treatment testing
17 of the integrity of the ultrafiltration control system and calculating predicted dialysate conductivity, to
18 be automated, thereby making dialysis safer and more reliable. *Id.* The incorporation of a battery-based
19 backup system also allowed important treatment parameters to be stored in the case of a power failure.
20 *Id.*

21 Two strategies were also developed and incorporated into hemodialysis machines to address
22 problems relating to fluid removal that occasionally occurred during hemodialysis. *Id.* at ¶ 17. These
23 strategies were based on: (1) varying the rate at which fluid was removed during dialysis, which is
24 known as ultrafiltration profiling;¹⁰ and (2) varying the sodium concentration in the dialysate throughout

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26
27 ¹⁰The extent to which ultrafiltration affects blood pressure is determined, in part, by how rapidly
28 excess fluid from other parts of the body enters the blood stream. *Id.* at ¶ 18. Ultrafiltration profiling
allows fluid removal to be increased during times of rapid vascular refilling and decreased when
vascular refilling is slow. *Id.* at ¶ 18.

1 the treatment, which is known as sodium profiling.¹¹ *Id.* Both ultrafiltration profiling and sodium
 2 profiling were made possible by the development of ultrafiltration control systems, more sophisticated
 3 dialysate proportioning systems, and the incorporation of more advanced microprocessor technology
 4 into dialysis machines. *Id.*

5 To perform ultrafiltration profiling, the speed of the ultrafiltration pump is varied as a function
 6 of treatment time according to some predetermined scheme. *Id.* at ¶ 19. In general, the volume of fluid
 7 prescribed for removal varies from one treatment to the next, even for the same patient. *Id.* Thus, for
 8 ultrafiltration to be generally applicable, the computer controlling ultrafiltration must be able to adjust
 9 the absolute ultrafiltration rates associated with a given ultrafiltration profile to match the desired fluid
 10 removal target for a particular treatment. *Id.*

11 In sodium profiling, a higher sodium concentration is used in the dialysate at the beginning of
 12 the hemodialysis treatment so that the sodium enters the blood and maintains osmotic pressure. *Id.* at
 13 ¶ 20. Later in the dialysis process, after most urea removal has taken place, the dialysate concentration
 14 is decreased to remove the added sodium. *Id.* To perform sodium profiling, the speed of the concentrate
 15 pump is manipulated to proportion more or less concentrate to fit a predetermined time-dependent
 16 sodium concentration profile. *Id.* This process requires a mechanism to monitor and change the sodium
 17 concentration throughout the treatment, which requires the entry of additional non-conductivity data.
 18 *Id.* at ¶ 21. When sodium profiling is used, the chemical composition and non-conductivity data is used
 19 in conjunction with an algorithm programmed into the computer which calculates the expected
 20 conductivity¹² of the dialysate at a particular point in the dialysis treatment and adjusts the conductivity
 21 alarm limits. *Id.*

23 ¹¹Rapid rates of solute removal have the effect of driving water out of the blood into other body
 24 compartments as the body attempts to maintain osmotic equilibrium between the different water pools
 25 in the body. *Id.* at ¶ 20. This movement of water opposes vascular refilling and can decrease blood
 26 volume and blood pressure, particularly if fluid is also being removed from the blood via a dialyzer.
Id. Sodium profiling is a means of maintaining osmotic equilibrium and maintaining patient blood
 volume. *Id.*

27 ¹²Conductivity is defined as the ability of a solution to pass electrical current. 131.18:25-30.
 28 Conductivity is used as a measurement of the electrolyte composition of the dialysate. *Id.* The
 conductivity of dialysate varies due to the temperature and the electrolyte composition of the dialysate.
Id.

Another feature that was eventually incorporated into hemodialysis machines was the addition of a "touch screen user interface." Touch screen user interfaces typically consist of hardware components and software components. Causey Decl. ISO Opp. to Baxter's MSJ at ¶ 16. The hardware components include a display, a touch screen that overlays the display, and associated electronics such as a touch screen controller. *Id.* at ¶ 17. The display – which is typically a CRT, LCD, or plasma display – displays images, numbers, and other information to the user. *Id.* at ¶ 18. The touch screen overlays the display and is touch-sensitive to allow the user to input information to control the device to which the touch screen user interface is connected. *Id.* at ¶ 19. The touch screen controller sends signals to the device indicating where on the touch screen overlay the user touched. *Id.* at ¶ 20. The touch screen controller is usually purchased from the supplier of the touch screen overlay. *Id.* at ¶ 20. As to the software, this is necessary to tell the device how to operate. *Id.* at ¶ 20. In the case of hemodialysis machines, the software – which runs in one or more of the microprocessors – controls the various pumps, valves, heaters, and other components of the hemodialysis machines. *Id.* at ¶ 21. The software also causes images to be created in simple or complex forms on the display portion of the touch screen user interface. *Id.* at ¶ 22. The operator of the machine responds to the images by touching the touch screen overlay, causing analog signals to be converted to digital representations as inputs to the software. *Id.* The software therefore provides the "instructions" to the hemodialysis machine for drawing images, buttons, and numbers presented on the display, reacting to the touching of the touch screen, and changing the operating behavior of the machine. *Id.*

2. The '476 and '027 Patents

The patents-in-suit disclose and claim various improvements to hemodialysis machines that allow better control, operation and monitoring of hemodialysis treatment. *See* 434:Abstract, 1:5-8, 131:Abstract, 1:12-15, 476:Abstract, 1:12-15, 027:Abstract, 1:8-11.¹³ For example, the patents-in-suit improved upon prior art dialysis machines by developing a new computer-controlled system that controls and monitors key functions such as dialysate preparation, ultrafiltration removal, and blood

¹³The patents-in-suit are cited to herein as "XXX.YY" with "XXX" denoting the patent number and "YY" denoting the claim number (*e.g.*, Claim 1 of the '476 Patent is "476.1.") or "XXX.YY:ZZ" with "XXX" denoting the patent number, "YY" denoting the claim, and "ZZ" denoting the line (*e.g.*, Claim 1 of the '476 Patent at lines 1 through 10 is "476.1.1-10.").

1 monitoring. 434:Abstract. The '434, '131 and '476 Patents claim dialysis machines with user/machine
 2 interfaces. *See, e.g.*, 434.26; 131.1; 476.7. The '131 Patent and '434 Patent also disclose integrating a
 3 touch screen interface through which treatment parameters can be set, monitored, and changed. *See*
 4 131.1, 434.26.

5 The '434 Patent is the parent application covering the particular use of a user/machine interface
 6 with a dialysis machine. *See* 434.26. The '131 Patent builds upon this technology by describing the
 7 ability to profile dialysis treatment parameters through the user/machine interface. *See* 131.1. The '476
 8 Patent discloses how the user/machine interface can be used to program profiled parameters that will
 9 change as needed during the course of the treatment to reach target levels of, for example, sodium and
 10 ultrafiltration, and how to customize these profiled parameters to the individual patient. *See* 476.7; *see*
 11 *also* 476:9:35-10:54; 38:10-15. The '027 Patent covers various safety enhancements. *See* 027.1. The
 12 '027 Patent, for example, claims an improved dialysis machine able to calculate the conductivity of
 13 dialysate made from a particular concentrate and automatically set alarm limits. *See* 027.1.

14 **a. Asserted Claims of the '476 Patent**

15 Claim 5 of the '476 Patent recites:

- 16 5. A method of providing operational instructions to a dialysate-producing
 17 machine having a memory and a capability of ultrafiltrating fluid from
 18 a patient according to a time-variable ultrafiltration profile, so as to
 19 enable the machine to produce dialysate having particular ultrafiltration
 20 characteristics at various times during use of the machine for a dialysis
 21 procedure, the method comprising:
- 22 (a) providing a user/machine interface configured as a touch screen
 23 operably connected to the dialysate-producing machine;
 - 24 (b) programming into the memory a first ultrafiltration profile;
 - 25 (c) providing on the touch screen an indicium enabling a user of the
 26 machine to recall the first ultrafiltration profile from the
 27 memory;
 - 28 (d) using the touch screen, displaying on the touch screen first and
 second intersecting axes defining a ultrafiltration profile region,
 the first axis corresponding to ultrafiltration rate, and the second
 axis corresponding to time; and
 - (e) touching the indicium provided in step (c) to cause the touch
 screen to display within the ultrafiltration profile region a
 second ultrafiltration profile substantially conforming to the
 first ultrafiltration profile.

1 476.5.

2 Claim 7 of the '476 Patent recites:

- 3 7. In an apparatus for performing hemodialysis comprising means for
 4 circulating dialysate through a dialysate compartment of a hemodialyzer
 5 and means for effecting extracorporeal circulating of blood through a
 6 blood compartment of the hemodialyzer, an improvement comprising:
- 7 (a) programmable memory means;
 - 8 (b) means for entering a time period into said memory means;
 - 9 (c) means for entering into said memory means a target cumulative
 10 value of a time-varying parameter to be achieved while
 11 operating the apparatus during the time period;
 - 12 (d) means for entering into said programmable memory means a
 13 proposed time-varying profile of the operational parameter to be
 14 executed by the apparatus during the time period, the proposed
 15 profile being representable as a plot of coordinates in a region
 16 defined by an ordinate of values of the parameter and a
 17 time-based abscissa, the plot defining a profile cumulative value
 18 of the parameter;
 - 19 (e) means, responsive to the entered time period and entered
 20 proposed profile, for comparing the profile cumulative value
 21 with the target cumulative value;
 - 22 (f) means, responsive to said means defined in (e), for changing the
 23 proposed profile along the ordinate so that the profile
 24 cumulative value is made equal to the target cumulative value;
 - 25 (g) means for entering the changed profile into said memory means
 26 in place of the proposed profile; and
 - 27 (h) means, responsive to said means defined in (g), for causing the
 28 apparatus to operate according to the changed shifted profile so
 as to enable the apparatus to achieve, while operating, the
 entered target cumulative value within the time period.

22 476.7.

23 **b. The Asserted Claims of the '027 Patent**

24 Claims 1, 2, 4, and 6 of the '027 Patent recite:

- 25 1. A kidney dialysis machine comprising:
- 26 (a) means for circulating dialysate at a dialysate conductivity
 27 through a dialysate circuit including a dialysate compartment
 28 for a dialyzer;

- (b) means for circulating blood from a dialysis patient through an extracorporeal blood circuit including a blood compartment of the dialyzer; and
 - (c) control means operable to receive chemical-composition data reflecting a particular selection of dialysate to be circulated and to calculate from the data an expected conductivity reading of the dialysate and to automatically set conductivity alarm limits around the expected conductivity reading.
2. A kidney dialysis machine as recited in claim 1 wherein said control means comprises means for receiving data regarding expected conductivity values of dialysates made from various concentrates, and means for processing the data so as to compare actual dialysate conductivity values against the corresponding expected conductivity value.
4. A kidney dialysis machine comprising:
 - (a) means for circulating dialysate through a dialysate circuit including a dialysate compartment of a dialyzer;
 - (b) means for circulating blood from a dialysis patient through an extracorporeal blood circuit including a blood compartment of the dialyzer; and
 - (c) a memory, the machine being operable to periodically save in said memory parameters associated with operation of the machine, the machine including means for automatically recalling from the memory, after a preselected duration of a power-off condition, the parameters according to which the machine was operating at the onset of the power-off condition.
6. A kidney dialysis machine comprising:
 - (a) means for circulating dialysate through a dialysate circuit including a dialysate compartment of a dialyzer;
 - (b) means for circulating blood from a dialysis patient through an extracorporeal blood circuit including a blood compartment of the dialyzer; and
 - (c) a memory for storing data including a value representing a net cumulative volume of liquid passed from the blood compartment to the dialysate compartment during a dialysis treatment performed using the machine, the machine being operable to automatically preserve in the memory, during a preselected duration of a power-off condition, said value and to restore machine operation according to said value when power is restored to the machine.

027.1, 2, 4, 6.

Claims 7, 8, and 10-16 of the '027 Patent recite:

- 1 7. A kidney dialysis machine, comprising:
 - 2 (a) a dialysate pump for circulating dialysate at a dialysate

3 conductivity through a dialysate circuit including a dialysate

4 compartment for a dialyzer; and

5 (b) a controller operable to receive non-conductivity data

6 concerning a particular selection of dialysate to be circulated

7 and to calculate from the data an expected conductivity reading

8 of the dialysate.
- 9 8. The kidney dialysis machine of claim 7, wherein the controller

10 automatically sets conductivity alarm limits around the expected

11 conductivity reading.
- 12 10. The kidney dialysis machine of claim 7, further comprising a data input

13 device connected to the controller, the data input device being for use

14 by an operator of the machine to provide the data to the controller.
- 15 11. The kidney dialysis machine of claim 10, wherein the data input device

16 comprises a touch screen.
- 17 12. The kidney dialysis machine of claim 7, further comprising a memory

18 connected to the controller, the memory being operable to store data

19 concerning an electrolytic profile of the dialysate resulting from a

20 baseline dilution of a respective dialysate concentrate with water, the

21 controller recalling the data from the memory when called upon to

22 calculate the expected conductivity of the dialysate made using the

23 dialysate concentrate.
- 24 13. The kidney dialysis machine of claim 12, wherein the memory stores an

25 algorithm for calculating the expected conductivity of the dialysate

26 made from the dialysate concentrate, the algorithm being recalled from

27 the memory by the controller when the controller is called upon to

28 calculate the expected conductivity of the dialysate made from the

 dialysate concentrate.
14. The kidney dialysis machine of claim 7, further comprising a

 proportioning pump for diluting a dialysate concentrate at a

 proportioning ratio with water to make the dialysate.
15. The kidney dialysis machine of claim 14, wherein the proportioning

 ratio is variable.
16. The kidney dialysis machine of claim 15, wherein the controller

 recalculates the expected dialysate conductivity and sets new

 conductivity alarm limits around the recalculated expected dialysate

 conductivity whenever the proportioning ratio is changed.

027.7, 8, 10-16.

3. The Alleged Prior Art References

a. The Seratron System

The "Seratron System" refers to the Cordis Dow Seratron™ Dialysis Control System ("Seratron Dialysis System"), the Seratron™ Modeling Programmer ("Modeling Programmer"), the Seratron™ Patient Recording and System Monitoring System ("PRSM"), and the printed publications that describe their structure, operation, and function. The Modeling Programmer and the PRSM were designed to work together with the Seratron Dialysis System to provide microprocessor-based controls and networking capability to the hemodialysis machine. *See* Ragsdale Decl. at ¶¶ 3, 18, 19.

b. The CMS08/A2008D System

The "CMS08/A2008D System" refers to the Fresenius Computer Modeling System 08 ("CMS08"), Fresenius A2008D Hemodialysis System ("A2008D"), and the printed publications that describe their structure, operation, and function. *See, e.g.,* McClenahan Decl. at Ex. 1. The CMS08 and the A2008D were designed to work together as a single device. *Id.*

c. The Sarns 9000

The Sarns 9000 is a touch screen-controlled perfusion system, also known as a heart-lung machine. McClenahan Decl. ISO Opp. to Baxter MSJ at Ex. J (Sarns Manual at F298967). The Sarns 9000 was offered for sale and sold as of 1988. *Id.* at Ex. O (Griewski Depo. at 143:15-17); *see id.* at Ex. J (Sarns Manual at F298974).

Perfusion systems such as the Sarns 9000 are intended to substitute for the heart and lungs of a patient who is undergoing cardiopulmonary bypass ("CPB") or valve surgery when the patient's heart must be stopped temporarily. *Id.* at Ex. J (Sarns Manual at F298979); Abernathy Decl. ISO Baxter MSJ at Ex. 4 (Griewski Depo. at 222-23). Using a heart-lung machine, a perfusionist diverts the patient's blood away from the body to an extracorporeal oxygenator, which removes carbon dioxide, oxygenates the blood, and then returns it to the patient. Abernathy Decl. ISO Baxter MSJ at Ex. 4 (Griewski Depo. at 185, 222-24).

The Sarns 9000 includes a touch screen user interface that displays data and operational parameters in both numerical and graphical formats, as illustrated by the "Main" and "Pulsatile" screens. The user can touch indicia on the touch screen to change the settings of the parameters. *Id.* at Ex. J (Sarns Manual at F298971, F299010-14, F299054-55). For example, the user can touch the "Pulse" button on the "Main" screen of the Sarns System to display the "Pulsatile" screen. *Id.* at Ex. J. (Sarns

Manual at F299014).

Using the Pulsatile¹⁴ screen, a user of the Sarns 9000 can set the pump speed to emulate the "pulsatile" pumping of the human heart. *Id.* at Ex. J (Sarns Manual at F299054-55). Specifically, the user can control, using the up and down arrows: (1) the number of pump cycles per minute (the "Rate" field); (2) the proportion of time the pump is at the higher output setting (the "Width" field); and (3) the pump speed during the lower output setting as a proportion of the pump speed during the higher output setting (the "Base" field). *Id.* In addition, the user can set the average volume of blood flow per unit time (the "Flow" field). *Id.* Once all of the components of pulsatile flow are entered, a square waveform is then displayed on the touch screen of the Sarns 9000 which graphically depicts the relationship between the maximum and minimum pumping phases of the pulsatile pump. *Id.*

The Sarns 9000 also includes five interchangeable roller pumps designed to offer the user flexibility to configure a variety of extracorporeal and drug delivery circuits as required by individual patients undergoing bypass procedures. *Id.* at Ex. J (Sarns Manual at F299036-F299045). Any one of the disclosed roller pumps is controllable via the touch screen interface and is capable of circulating fluids at controlled rates. *Id.* at Ex. J (Sarns Manual at F298871, F298978-79, F298986-87, F299061-62); *see also* Riley Decl. at ¶ 6.

The Sarns Manual states that the machine's use is for cardiopulmonary by-pass procedures ("CPB") only. In fact, it explicitly lists as "Indications" the following:

The Sarns 9000 Perfusion System is indicated for use in extracorporeal circulation of blood for arterial perfusion, regional perfusion, and cardiopulmonary by-pass procedures, when used by a qualified perfusionist who is experienced in the operation of Sarns or similar equipment.

Abernathy Decl. ISO Baxter MSJ at Ex. 3 (Sarns Manual at F298979).

According to Fresenius' expert, Mr. Griewski, the Sarns Manual does not disclose that the Sarns 9000 can function as a hemodialysis machine or perform functions related to hemodialysis. *See* Abernathy Decl. ISO Baxter MSJ at Ex. 4 (Griewski Depo. at 216-18).

LEGAL STANDARD

¹⁴Pulsatile flow is a type of blood flow that simulates the beating of the heart sometimes used during a cardiopulmonary bypass procedure when a patient's heart is stopped. *See* Abernathy Decl. ISO Baxter MSJ at Ex. 4 (Griewski Depo. at 221-22).

A. Legal Standard For Summary Judgment in Patent Disputes

Under Federal Rule of Civil Procedure 56, a court may properly grant a motion for summary judgment if the pleadings and materials demonstrate that there is "no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). A dispute about a material fact is genuine "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). Summary judgment may be granted in favor of a defendant on an ultimate issue of fact where the defendant carries its burden of "pointing out to the district court that there is an absence of evidence to support the nonmoving party's case." *Celotex*, 477 U.S. at 325; *see Johnston v. IVAC Corp.*, 885 F.2d 1574, 1577 (Fed. Cir. 1989).

To withstand a motion for summary judgment, the non-movant must show that there are genuine factual issues which can only be resolved by the trier of fact. *Anderson*, 477 U.S. at 250. The nonmoving party may not rely on the pleadings but must present specific facts creating a genuine issue of material fact. *T.W. Elec. Serv. v. Pacific Elec. Contractors Ass'n*, 809 F.2d 626, 630 (9th Cir. 1987). The court's function, however, is not to make credibility determinations. *Anderson*, 477 U.S. at 249. The inferences to be drawn from the facts must be viewed in a light most favorable to the party opposing the motion. *T.W. Elec. Serv.*, 809 F.2d at 631.

It is not the task of the district court to scour the record in search of a genuine issue of triable fact. *Keenan v. Allen*, 91 F.3d 1275, 1279 (9th Cir. 1996). The nonmoving party has the burden of identifying with reasonable particularity the evidence that precludes summary judgment. *Id.* If the nonmoving party fails to do so, the district court may properly grant summary judgment in favor of the moving party. *See Carmen v. San Francisco Unified School District*, 237 F.3d 1026, 1028-29 (9th Cir. 2001) (even if there is evidence in the court file which creates a genuine issue of material fact, a district court may grant summary judgment if the opposing papers do not include or conveniently refer to that evidence). Although the district court has discretion to consider materials in the court file not referenced in the opposing papers, it need not do so. *Id.* at 1029. "The district court need not examine the entire file for evidence establishing a genuine issue of fact." *Id.* at 1031. However, when the parties file cross-motions for summary judgment, the district court must consider all of the evidence submitted in

support of both motions to evaluate whether a genuine issue of material fact exists precluding summary judgment for either party. *The Fair Housing Council of Riverside County, Inc. v. Riverside Two*, 249 F.3d 1132, 1135 (9th Cir. 2001).

A court may grant a summary judgment motion in a patent case, as in any other case. *Avia Group Int'l, Inc. v. L.A. Gear Cal., Inc.*, 853 F.2d 1557, 1561 (Fed. Cir. 1988). In fact, the Federal Circuit has expressly recognized that summary judgment of invalidity is proper, including invalidity based on obviousness under 35 U.S.C. § 103. *See, e.g., McNeil-PPC, Inc. v. L. Perrigo Co.*, 337 F.3d 1362, 1367 (Fed. Cir. 2003) (affirming grant of summary judgment of invalidity based on obviousness). But "in considering the [summary judgment] motion, the court must view the evidence in the most favorable light to the non-movant and draw all reasonable inferences in the non-moving party's favor." *Tillotson, Ltd. v. Walbo Corp.*, 831 F.2d 1033, 1037 (Fed. Cir. 1987).

Since summary judgment must be supported by "facts as would be admissible in evidence," *see* Fed. R. Civ. P. 56(e), scientific evidence produced in support of or in opposition to a motion for summary judgment must meet the standards of relevance and reliability articulated in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993). *See Seaboard Lumber Co. v. United States*, 308 F.3d 1283, 1301 (Fed. Cir. 2002). The Supreme Court in *Daubert* described this inquiry as follows:

Faced with a proffer of expert scientific testimony . . . the trial judge must determine . . . whether the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue. This entails a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue.

509 U.S. at 590.

B. Claim Construction

1. Intrinsic Evidence

"It is well-settled that, in interpreting an asserted claim, the court should look first to the intrinsic evidence of record, *i.e.*, the patent itself, including the claims, the specification, and, if in evidence, the prosecution history." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996) (citing *Markman*, 52 F.3d at 979). In the context of the intrinsic evidence, the language of the claims

1 themselves is the starting point. *See id.* Words in a claim are generally given their ordinary and
2 customary meaning as understood by one of ordinary skill in the art. *See id.*; *see also Dow Chem. Co.*
3 *v. Sumitomo Chem. Co.*, 257 F.3d 1364, 1373 (Fed. Cir. 2001) ("[A] technical term used in a patent claim
4 is interpreted as having the meaning a person of ordinary skill in the field of invention would understand
5 it to mean.").

6 "Although words in a claim are generally given their ordinary and customary meaning, a patentee
7 may choose to be his own lexicographer and use terms in a manner other than their ordinary meaning,
8 provided the special definition of the term is clearly stated in the specification." *Vitronics*, 90 F.3d at
9 1582; *see also Irdeto Access, Inc. v. Echostar Satellite Corp.*, 383 F.3d 1295, 1300 (Fed. Cir. 2004).
10 Therefore, it is necessary to review the specification to determine whether the patentee has used terms
11 inconsistent with their ordinary and customary meaning. *See Vitronics*, 90 F.3d at 1582. The
12 specification acts as a dictionary when it expressly or impliedly defines a term used in the claim. *See*
13 *Vitronics*, 90 F.3d at 1582 (citing *Markman*, 52 F.3d at 979); *see also Irdeto*, 383 F.3d at 1300.

14 In examining the specification, however, the court must not read limitations from the
15 specification into the claims. *See Burke, Inc. v. Bruno Indep. Living Aids, Inc.*, 183 F.3d 1334, 1340
16 (Fed. Cir. 1999). "[E]ven where a patent describes only a single embodiment, claims will not be 'read
17 restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using "words
18 or expressions of manifest exclusion or restriction"'" *Innova/Pure Water, Inc. v. Safari Water Filtration*
19 *Sys.*, 381 F.3d 1111, 1117 (Fed. Cir. 2004) (citing *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898,
20 906 (Fed. Cir. 2004)); *see AstraZeneca AB v. Mut. Pharm. Co.*, 384 F.3d 1333, 1340 (Fed. Cir. 2004)
21 (noting where general summary or description of the invention describes a feature of the invention and
22 criticizes other products that lack that same feature, this operates as a clear disavowal of these other
23 products and processes using these products); *see also Home Diagnostics*, 381 F.3d at 1357 ("[T]he
24 applicant's choice to describe only a single embodiment does not mean the patent clearly and
25 unambiguously disavowed other embodiments.").

26 Finally, if it is entered into evidence, the court must examine the prosecution history of the
27 patent. *See Dow Chem.*, 257 F.3d at 1373; *Vitronics*, 90 F.3d at 1582. The prosecution history contains
28 the complete record of the proceedings before the Patent and Trademark Office, and may include

1 express representations made by the applicant regarding the scope of the claims. *See Vitronics*, 90 F.3d
2 at 1582. The court examines the prosecution history to determine "whether the patentee has
3 'relinquished a potential claim construction in an amendment to the claim or in an argument to overcome
4 or distinguish a reference.'" *Dow Chem.*, 257 F.3d at 1373 (citing *Interactive Gift Exp., Inc. v.*
5 *Compuserve Inc.*, 256 F.3d 1323, 1331 (Fed. Cir. 2001)); *see also Pall Corp. v. PTI Technologies*, 259
6 F.3d 1383, 1392 (Fed. Cir. 2001) ("[I]t is well established that '[t]he prosecution history limits the
7 interpretation of claim terms so as to exclude any interpretation that was disclaimed during
8 prosecution.'" (citing *Southwall Technologies, Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1576 (Fed. Cir.
9 1995)). To balance the importance of public notice and the right of patentees to seek broad patent
10 coverage, the Federal Circuit has "consistently rejected prosecution statements too vague or ambiguous
11 to qualify as a disavowal of claim scope." *Omega Eng'g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1325 (Fed.
12 Cir. 2003) (citations omitted). The Federal Circuit requires the alleged disavowing statements to be both
13 so clear as to show reasonable clarity and deliberateness, and so unmistakable as to be unambiguous
14 evidence of disclaimer. *Id.* (citations omitted). "Consequently, for prosecution disclaimer to attach, [the
15 Federal Circuit] requires that the alleged disavowing actions or statements made during prosecution be
16 both clear and unmistakable." *Id.* at 1326 (citations omitted).

17 2. Extrinsic Evidence

18 In most cases, an examination of the intrinsic evidence will be sufficient to resolve any
19 ambiguity in the disputed claim and it would be improper to rely on extrinsic evidence. *See Vitronics*,
20 90 F.3d at 1583 (citing *Pall Corp. v. Micron Separations, Inc.*, 66 F.3d 1211, 1216 (Fed. Cir. 1995)).
21 Extrinsic evidence may be used to define the claim only if the claim language remains "genuinely
22 ambiguous" after consideration of the intrinsic evidence. *See id.* However, "it is entirely appropriate,
23 perhaps even preferable, for a court to consult trustworthy extrinsic evidence to ensure that the claim
24 constructions it is tending to from the patent file is not inconsistent with clearly expressed, plainly
25 apposite, and widely held understandings in the pertinent technical field." *AFG Indus.*, 239 F.3d at 1249
26 (quoting *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1309 (Fed. Cir. 1999)); *see also*
27 *Bell v. Howell Document Mgmt. Prods. Co.*, 132 F.3d 701, 706 (Fed. Cir. 1998); *Mantech Envtl. Corp.*
28 *v. Hudson Envtl. Servs.*, 152 F.3d 1368, 1373 (Fed. Cir. 1998).

When the specification explains and defines a term used in the claims, without ambiguity or incompleteness, there is no need to search further for the meaning of the term. However, when such definition is challenged it is often appropriate, despite facial clarity and sufficiency of the specification and the prosecution history, to receive evidence of the meaning and usage of terms of art from persons experienced in the field of the invention.

ATD Corp. v. Lydall, Inc., 159 F.3d 534, 540 (Fed. Cir. 1998) (citing Fed. R. Evid. 702–706; *Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1478 (Fed. Cir. 1998)). A court may hear all relevant testimony – including expert testimony – so long as it does not accord weight to expert testimony that contradicts the clear language of the claim. *See Vitronics*, 90 F.3d at 1584.

C. Invalidity

Patents are presumed to be valid and the burden of establishing the invalidity of a patent rests on the party asserting invalidity. *See* 35 U.S.C. § 281. The factual findings supporting a conclusion of invalidity must be proven by clear and convincing evidence. *N.V. Akzo v. E.I. DuPont de Nemours*, 810 F.2d 1148, 1151 (Fed. Cir.1987).

1. Legal Standard for Anticipation

A patent claim is invalid as anticipated if "the invention was patented or described in a printed publication in this . . . country . . . more than one year prior to the date of the application for patent in the United States." 35 U.S.C. § 102(b). Anticipation requires that a single prior art reference disclose each and every limitation of the claimed invention. *Schering Corp. v. Geneva Pharmas.*, 339 F.3d 1373, 1379 (Fed. Cir. 2003). A prior art reference may, however, anticipate "without disclosing a feature of the claimed invention if that missing characteristic is necessarily present, or inherent, in the single anticipating reference." *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1343 (Fed. Cir. 2005); *see also Cont'l Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed. Cir. 1991).

In determining invalidity due to anticipation, the first step involves the proper interpretation of the claims. *Elmer v. ICC Fabricating, Inc.*, 67 F.3d 1571, 1574 (Fed. Cir.1995). To ascertain the meaning of the claims, the court looks to the claim language, the specification, and the prosecution history. *SmithKline Diagnostics, Inc. v. Helena Labs. Corp.*, 859 F.2d 878, 882 (Fed. Cir. 1989). The other claims and expert testimony are also relevant. *Id.* "The claims should be construed as one skilled in the art would construe them." *Id.*

1 The second step involves determining whether the limitations of the claims as properly
2 interpreted are met by the prior art. *Id.* "Invalidity for anticipation requires that all of the elements and
3 limitations of the claim are found within a single prior art reference." *Scripps Clinic & Research Fdn.*
4 *v. Genentech, Inc.*, 927 F.2d 1565, 1576 (Fed. Cir.1991) ("There must be no difference between the
5 claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of
6 the invention"); *Hazani v. U.S. Intern. Trade Com'n*, 126 F.3d 1473, 1477 (Fed.Cir.1997).

7 An anticipation analysis involves a three-part inquiry. First, the trier of fact must determine
8 whether the challenging reference is prior art. *Mahurkar v. C.R. Bard, Inc.*, 79 F.3d 1572, 1576-78 (Fed.
9 Cir. 1996); *Del-mar Eng'g, Lab v. United States*, 524 F.2d 1178, 1184 (Ct. Cl. 1975). Second, the fact
10 finder must ascertain that the prior art is enabling as to put the invention in the public's possession. *Akzo*
11 *N.V. v. U.S. Int'l Trade Comm'n*, 808 F.2d 1471, 1479 (Fed. Cir. 1986), *cert. denied*, 482 U.S. 909
12 (1987). However, prior art patent references are presumed enabled. *In re Sasse*, 629 F.2d 675, 681
13 (C.C.P.A.1980). In the third step, the trier of fact must ascertain whether the doctrine of identity applies,
14 *i.e.*, whether each element of the accused claim is present either expressly or inherently in a single prior
15 reference. *Kalman v. Kimberly-Clark Corp.*, 713 F.2d 760, 771 (Fed.Cir.1983), *cert. denied*, 465 U.S.
16 1026 (1984).

17 2. Legal Standard for Obviousness

18 Pursuant to 35 U.S.C. § 103, patent claims are invalid "if the differences between the subject
19 matter sought to be patented and the prior art are such that the subject matter as a whole would have
20 been obvious at the time the invention was made to a person having ordinary skill in the art to which
21 said subject matter pertains." 35 U.S.C. § 103(a). "It is black letter law that the ultimate question of
22 obviousness is a question of law." *Richardson-Vicks*, 122 F.3d at 1479.

23 An obviousness analysis is based on four underlying factual inquiries: (1) the scope and content
24 of the prior art; (2) the differences between the claims and the prior art; (3) the level of ordinary skill
25 in the pertinent art; and (4) secondary considerations of nonobviousness, such as commercial success,
26 copying, or long felt but unresolved need in the art. *Graham v. John Deere Co.*, 383 U.S. 1, 17-18
27 (1966). Secondary considerations of non-obviousness can include commercial success, long felt but
28 unresolved need, and failure of others to solve the problem. *Id.*; *see also B.F. Goodrich Co. v. Aircraft*

1 *Braking Sys. Corp.*, 72 F.3d 1577, 1582 (Fed. Cir. 1996). Such considerations are not material to the
 2 issue of invalidity, however, unless there is a nexus between the evidence and the features described in
 3 the claims. *In re GPAC Inc.*, 57 F.3d 1573, 1580 (Fed. Cir. 1995).

4 Precedent also requires a suggestion, teaching, or motivation to combine the references relied
 5 upon, or to modify a single reference such that the claimed invention is practiced. *Brown & Williamson*,
 6 229 F.3d at 1124-25. Evidence of a motivation to combine "may flow from the prior art references
 7 themselves, the knowledge of one of ordinary skill in the art, or in some cases, from the nature of the
 8 problem to be solved." *Id.* at 1125 (citing *Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc.*, 75 F.3d
 9 1568, 1573 (Fed. Cir. 1996)).

10 **3. Legal Standards for Enablement and Indefiniteness**

11 A patent grant is issued in exchange for an enabling disclosure of an invention. *White Consol.*
 12 *Indus., Inc. v. Vega Servo-Control, Inc.*, 713 F.2d 788, 791 (Fed. Cir. 1983). The enablement
 13 requirement of 35 U.S.C. § 112, paragraph 1, provides, in relevant part, that:

14 The [patent] specification shall contain a written description of the invention,
 15 and the manner and process of making and using the [invention], in such full,
 16 clear, concise, and exact terms as to enable any person skilled in the art to
 which it pertains . . . to make and use the [invention].

17 35 U.S.C. § 112. The enablement requirement is met "when one skilled in the art, after reading the
 18 specification, could practice the claimed invention without undue experimentation." *AK Steel Corp. v.*
 19 *Sollac & Ugine*, 344 F.3d 1234, 1244 (Fed. Cir. 2003). Enablement is a question of law based on
 20 underlying facts, which is tested as of the effective filing date of the application. *Id.*

21 Enablement is determined at the time the patent application was filed. *Ajinomoto Co., Inc. v.*
 22 *Archer-Daniels-Midland Co.*, 228 F.3d 1338, 1345 (Fed. Cir. 2000), *cert. denied*, 532 U.S. 1019 (2001).
 23 Determining whether a disclosure of a patent satisfies the enablement requirement is a question of law.
 24 *Atlas Powder Co. v. E.I. DuPont de Nemours & Co.*, 750 F.2d 1569, 1576 (Fed. Cir. 1984). The legal
 25 conclusion of enablement rests on factual underpinnings. *Union Pacific Resources Co. v. Chesapeake*
 26 *Energy Corp.*, 236 F.3d 684, 690 (Fed. Cir. 2001).

27 A decision on the issue of enablement "requires determination of whether a person skilled in the
 28 pertinent art, using the knowledge available to such a person and the disclosure in the patent document,

1 could make and use the claimed invention without undue experimentation." *Northern Telecom, Inc. v.*
2 *Datapoint Corp.*, 908 F.2d 931, 941 (Fed. Cir. 1990). Factors to be considered in determining whether
3 a disclosure would require undue experimentation include: (1) the quantity of experimentation
4 necessary; (2) the amount of direction or guidance presented; (3) the presence or absence of working
5 examples; (4) the nature of the invention; (5) the state of the prior art; (6) the relative skill of those in
6 the art; (7) the predictability or unpredictability of the art; and (8) the breadth of the claims. *In re*
7 *Wands*, 858 F.2d 731 (Fed. Cir. 1988); *Enzo Biochem v. Calgene, Inc.*, 188 F.3d 1362, 1371 (Fed. Cir.
8 1999).

9 While some experimentation does not preclude enablement, the amount of experimentation must
10 not be unduly extensive. *Atlas Powder Co.*, 750 F.2d at 1576. The test for undue experimentation
11 allows for a considerable amount of experimentation if it is merely routine or if the patent specification
12 provides a reasonable amount of guidance with respect to the direction in which the experimentation
13 should proceed. *Johns Hopkins University v. CellPro, Inc.*, 152 F.3d 1342, 1360 (Fed. Cir. 1998).

14 35 U.S.C. § 112 also requires that a patent specification conclude with one or more claims
15 "particularly pointing out and distinctly claiming subject matter which the applicant regards as his
16 invention." 35 U.S.C. § 112, 2. A finding of definiteness is a question of law for the Court to decide.
17 *Exxon Research & Eng'g Co. v. United States*, 265 F.3d 1371, 1376 (Fed. Cir. 2001). The standard for
18 assessing whether a claim is sufficiently definite is whether "one skilled in the art would understand the
19 bounds of the claim when read in light of the specification." *Id.* at 1375. "If the meaning of the claim
20 is discernible, even though the task may be formidable and the conclusion may be one over which
21 reasonable persons will disagree, . . . the claim [is] sufficiently clear to avoid invalidity on indefiniteness
22 grounds." *Id.* at 1376 (emphasis added) (citations omitted); *see also Allen Archery, Inc. v. Browning*
23 *Mfg. Co.*, 819 F.2d 1087, 1092 (Fed. Cir. 1987) (testimony by witnesses who express difficulty in
24 comprehending the claim language is not enough to find the claim indefinite).

25 ANALYSIS

26 In its Motion for Summary Judgment of Invalidity of the Asserted Claims of U.S. Patent Nos.
27 5,326,476 and 5,744,027, Fresenius seeks a summary judgment finding that the asserted claims of the
28 '476 and '027 Patents are invalid on the following grounds: (1) that claim 7 of the '476 Patent is

1 anticipated under 35 U.S.C. § 102(b) by the CMS08/A2008D System; (2) that claim 5 of the '476 Patent
2 is either indefinite and/or non-enabling under 35 U.S.C. § 112 or rendered obvious under 35 U.S.C. §
3 103(a) by a combination of the CMS08/A2008 System and the Sarns System; (3) that claims 1, 2, 4, 6-8,
4 10, and 12-16 of the '027 Patent are anticipated under 35 U.S.C. § 102(b) by the Seratron System; and
5 (4) that claim 11 of the '027 Patent is rendered obvious under 35 U.S.C. § 103(a) by a combination of
6 the Seratron System and the Sarns System.

7 **A. The '476 Patent**

8 The first argument set forth in Fresenius' Motion for Summary Judgment is that claims 5 and 7
9 of the '476 Patent are invalid because claim 7 is anticipated by the CMS08/A2008D System and claim
10 5 is either indefinite and/or non-enabling under 35 U.S.C. § 112 or rendered obvious by a combination
11 of the CMS08/A2008D System and the Sarns System

12 **1. The Status of the Prior Art**

13 **a. The CMS08/A2008D System**

14 Before the Court can analyze Fresenius' anticipation and obviousness defenses pertaining to the
15 asserted claims of the '476 Patent, the Court must first address whether the CMS08 System is properly
16 considered prior art. To establish priority, Fresenius relies on a machine known as the CMS08 System,
17 which it claims was "first sold in the United States in 1985," as well as its manual. *See* Abernathy Decl.
18 ISO Opp. to Fresenius MSJ II at Ex. 8 (CMS08 Handbook at F330311-80). In its Opposition, Baxter
19 alleges that Fresenius has not shown, by clear and convincing evidence, that the CMS08 System is prior
20 art because there is no evidence that the CMS08 was ever on sale, sold, or in public use in the United
21 States before April 19, 1990, the critical date.¹⁵

22 To prove that the CMS08 System was on sale in the United States by the critical date, Fresenius
23 has produced the following evidence: (1) a 1985 "purchase order" from Seratronics to Fresenius AG;
24 (2) "invoices" showing a shipment in 1985 of the CMS08 System to Seratronics; and (3) certain CMS08
25 System brochures. Thus, based on the factual record before the Court, Baxter is incorrect that there is
26

27 ¹⁵On its face, the '476 Patent claims priority to its parent application Ser. No. 07/688,174, filed
28 April 19, 1991. For the purposes of this Motion, it will be assumed that the critical date is April 19,
1990. *See* 35 U.S.C. § 102(b).

1 no evidence pertaining to whether the CMS08 System was on sale in the United States by the critical
2 date. However, Baxter is correct that there are disputed factual issues pertaining to whether these
3 documents prove that a "sale" took place.

4 First, despite Fresenius' contention that its sales evidence is "overwhelming," none of Fresenius'
5 witnesses could even remember whether an actual sale took place. For example, Dr. Lipps¹⁶ testified
6 that he "believes we sold them [CMS08], but [he] would have to go back 20 years." *Id.* at Ex. 11 (Lipps
7 Depo. at 85:16-86:5). He further testified that the machines may have been sold to researchers, but
8 could not identify any particular sales. *Id.* at Ex 11 (Lipps Depo. at 81:15-25, 85:25-86:8). With respect
9 to the "invoices," Fresenius has admitted that these documents do not, alone, show sales or public use
10 of the CMS08. *See id.* at Ex. 15. Further, Mr. Folden¹⁷ testified that the invoices were missing the price
11 term. *Id.* at Ex. 10 (Folden Depo. at 182:1-183:1). As to the purchase order, Mr. Folden's testimony
12 also creates some doubt as to whether this document indicates that an *intercompany* sale took place, or
13 whether there was merely an *intracompany transfer* of technology between Seratronics and Fresenius,
14 who were affiliated entities at the time.¹⁸ *See id.*

15 Additionally, Fresenius' expert witness, Dr. Ward, was asked about Fresenius' sales documents
16 during his deposition, but admitted that he could not translate them and had never been provided with
17 a translation. *Id.* at Ex. 16 (Ward Depo. at 75:20-78:8; 67:15-22). As to the brochures, Dr. Ward
18 testified that his "memory is not that good" and could only state that the advertising materials
19 "impl[ied]" that they had been distributed in the United States. *Id.* at Ex. 16 (Ward Depo. at 72:10-15).
20 As Baxter points out, however, all but one brochure is undated and they do not indicate, on their face,
21 that they were actually distributed in the United States. *Id.* at Ex. 12 (CMS08 Brochures at F090715-16,
22 BA013668-71, F310404-21, F310384-403). Further, a product is only "on-sale" if there is an offer for
23 sale in a contractual sense, such as is indicated under the Uniform Commercial Code. *Group One Ltd.*

25 ¹⁶Dr. Lipps was Seratronics' President and CEO from 1982 to 1994.

26 ¹⁷Mr. Folden was Fresenius' Rule 30(b)(6) designee on the topic.

27 ¹⁸From 1984 to 1985, Seratronics became affiliated with Fresenius as a distributor. *Id.* at Ex. 11
28 (Lipps. Depo. at 26:23-27:1; 28:16-29:8). According to Dr. Ward, it eventually "morphed" into
Fresenius USA. *Id.* at Ex. 16 (Ward Depo. at 76:12-15).

1 v. *Hallmark Cards, Inc.*, 254 F.3d 1041, 1047-48 (Fed. Cir. 2001). Undated advertisements, such as
2 these brochures, do not qualify as an offer for sale. *See id.*

3 While Fresenius relies on *Buildex Inc. v. Kason Industries, Inc.*, 849 F.2d 1461, 1463 (Fed. Cir.
4 1988), to support its assertion that it need not prove that any sales were actually consummated, the facts
5 here – which are considerably less clear and are in dispute – are not analogous to *Buildex*. *Id.* In sum,
6 the numerous factual issues here simply cannot be resolved on summary judgment.

7 Nevertheless, Fresenius has convincingly shown that the CMS08 System *manual* constitutes
8 prior art pursuant to 35 U.S.C. § 102(b) because it is a "printed publication." *See* McClenahan Decl.
9 at Ex. 1 (CMS08 System manual). Specifically, Fresenius has shown that the manual was published in
10 1985 and that the CMS08 machine, itself, was discussed in various other publications in Europe
11 throughout the mid-1980's. *See id.* at Exs. 5-10. Baxter has not identified anything in the record that
12 creates a factual dispute as to whether the manual fulfills the requirements of 35 U.S.C. § 102(b).¹⁹

13 Accordingly, the CMS08 System manual, which is attached as Exhibit 1 to the McClenahan
14 Declaration, shall be considered as prior art for the purposes of evaluating the instant Motion for
15 Summary Judgment.

16 Before the Court can proceed to its anticipation analysis, however, there is yet another
17 preliminary issue that the Court must resolve: (1) whether Fresenius is entitled to "combine" the CMS08
18 System with the A2008D System in order to prove anticipation. In its Opposition, Baxter asserts, in a
19 footnote, that it "disputes Fresenius' suggestion that the CMS08 is combinable with the 2008D for
20 purposes of anticipation." Opp. at 18 n. 14.

21 While it has long been held that anticipation requires that a *single* prior art reference disclose
22 each and every limitation of the claimed invention, the Federal Circuit has also held that "[m]aterial not
23 explicitly contained in the single, prior art document may still be considered for purposes of anticipation
24 if that material is incorporated by reference into the document." *Advanced Display Systems, Inc. v. Kent*
25 *State Univ.*, 212 F.3d 1272, 1282 (Fed. Cir. 2000); *Schering Corp. v. Geneva Pharmas.*, 339 F.3d 1373,
26 1379 (Fed. Cir. 2003). "Incorporation by reference provides a method for integrating material from

27
28 ¹⁹Instead, Baxter has attempted to strike the manual as an unauthenticated "translation." As set forth in the separate Order addressing Baxter's Motion to Strike, this argument is without merit.

various documents into a host document – a patent or printed publication in an anticipation determination – by citing such material in a manner that makes clear that the material is effectively part of the host document as if it were explicitly contained therein." *Advanced Display Systems*, 212 F.3d at 1282. Here, as noted above, the Court is relying upon the CMS08 System *manual* in order to evaluate Fresenius' anticipation defense, and the CMS08 System *manual* clearly refers to, and incorporates by reference, the A2008D. *See, e.g.*, McClenahan Decl. at Ex. 1 (CMS08 System Handbook at F330316) ("The CMS08 System 08 . . . is a computer driver system with V.D.U. display for the programmed control of treatment parameters. **As an addition to the A2008** it permits the time dependent change of ultrafiltration rate and a maximum of three electrolyte concentrations during dialysis.") (emphasis added). In fact, the A2008D System is mentioned on nearly every page of the CMS08 System manual. *See, e.g., id.* at Ex. 1. Accordingly, Baxter's argument that the Court may not consider the A2008D System as being part of the anticipatory prior art reference is without merit.

2. Claim 7 of the '476 Patent

Having concluded that the CMS08/A2008D System can be considered as prior art, the next step is to analyze Fresenius' arguments with respect to the asserted claims of the '476 Patent. Fresenius first alleges that the CMS08/A2008D System anticipates claim 7 because it embodies each and every element of claim 7 of the '476 Patent.

Claim 7 of the '476 Patent recites:

7. In an apparatus for performing hemodialysis comprising means for circulating dialysate through a dialysate compartment of a hemodialyzer and means for effecting extracorporeal circulating of blood through a blood compartment of the hemodialyzer, an improvement comprising:²⁰

(a) programmable memory means;²¹

²⁰According to Fresenius, neither party disputes that the CMS08/A2008D System is an apparatus for performing hemodialysis. Further, since this claim is directed to an "improvement," neither party disputes that the limitation "means for circulating dialysate through a dialysate compartment of a hemodialyzer and means for effecting extracorporeal circulating of blood through a blood compartment of the hemodialyzer" is in the prior art. *See* M.P.E.P., § 2129; *see also* Ward Decl. at ¶ 42.

²¹According to Fresenius, this element is met because the CMS08 has a programmable memory. *See* McClenahan Decl. at Ex. 1 (CMS08 System Handbook at F330318, F330326, F330339, F330349); *see also* Ward Decl. at ¶ 42. Fresenius contends that the CMS08 also meets this limitation because it includes a battery-supported RAM memory in which variables and constants can be stored when the

- (b) means for entering a time period into said memory means;²²
- (c) means for entering into said memory means a target cumulative value of a time-varying parameter to be achieved while operating the apparatus during the time period;²³
- (d) means for entering into said programmable memory means a proposed time-varying profile of the operational parameter to be executed by the apparatus during the time period, the proposed profile being representable as a plot of coordinates in a region defined by an ordinate of values of the parameter and a time-based abscissa, the plot defining a profile cumulative value of the parameter;²⁴
- (e) means, responsive to the entered time period and entered proposed profile, for comparing the profile cumulative value with the target cumulative value;
- (f) means, responsive to said means defined in (e), for changing the proposed profile along the ordinate so that the profile cumulative value is made equal to the target cumulative value;
- (g) means for entering the changed profile into said memory means in place of the proposed profile;²⁵ and
- (h) means, responsive to said means defined in (g), for causing the apparatus to operate according to the changed shifted profile so as to enable the apparatus to achieve, while operating, the

CMS08 is switched off. McClenahan Decl. Ex. 1 (CMS08 System Handbook at F330326); Ward Decl. at ¶ 42.

²²Fresenius states that this element is met because the CMS08 System has a user interface and microprocessor that permits the user to enter a "[d]ialysis time from 0 to 7 hours and 30 minutes" into programmable memory. *See* McClenahan Decl. at Ex. 1 (CMS08 System Handbook at F330318, F330333, F330342, F330345); Ward Decl. at ¶ 43.

²³This element is met because the CMS08's machine interface and microprocessor permit the user to enter into the memory a target cumulative value of an ultrafiltration (UF) profile (a time-varying parameter) to be achieved during the dialysis period. McClenahan Decl. at Ex. 1 (CMS08 System Handbook at F330342, F330348); Ward Decl. at ¶ 44.

²⁴This element is met because the CMS08's machine interface and microprocessor also permit the user to enter into the memory a proposed time-varying profile of an operational parameter (*e.g.* a UF profile). McClenahan Decl. at Ex. 1 (CMS08 System Handbook at F330342, F330347-48); Ward Decl. at ¶ 45. This profile is executed by the CMS08 when requested by the user. McClenahan Decl. at Ex. 1 (CMS08 System Handbook at F330327); Ward Decl. at ¶ 45. The proposed profile is represented as a plot of coordinates in a region defined by an ordinate of UF values and a time-based abscissa, and defining a cumulative value of the volume of UF to be removed from the patient. McClenahan Decl. at Ex. 1 (CMS08 System Handbook at F330341); Ward Decl. at ¶ 45.

²⁵Fresenius contends that this element is met because the CMS08 includes a microprocessor that allows the changed profile to be entered into memory in place of the proposed profile. *See* McClenahan Decl. at Ex. 1 (CMS08 System Handbook at F330318, F330349); *see also* Ward Decl. at ¶ 48.

entered target cumulative value within the time period.²⁶

476.7.

Neither party disputes that the CMS08/A2008 embodies elements (a)-(d) and (g)-(h) of claim 7. The dispute solely focuses on whether Fresenius has met its burden of proof as to claim elements (e) and (f) of claim 7. Again, these claim elements require:

7(e): means, responsive to the entered time period and the entered proposed profile, for comparing the profile cumulative value with the target cumulative value.

7(f): means, responsive to said means defined in (e), for changing the proposed profile along the ordinate so that the profile cumulative value is made equal to the target cumulative value.

476.7.

In order for the Court to determine anticipation, it must first construe the disputed claim elements. Both parties agree that elements (e) and (f) are means-plus-function limitations governed by 35 U.S.C. § 112. Section 112 provides that "[a]n element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof." 35 U.S.C. § 112. The construction of a means-plus-function limitation is a two-step process. *JVW Enterprises, Inc. v. Interact Accessories, Inc.*, 424 F.3d 1324, 1330 (Fed. Cir. 2005). First, the Court must determine the claimed function. *Id.* Second, the Court must identify the corresponding structure in the written description that performs that function. *Id.*

Here, Baxter asserts that the functional requirements of both elements (e) and (f) should be given their plain and ordinary meaning. In other words, the claimed function of element (e) is simply "*comparing* the profile cumulative value with the target cumulative value." Similarly, the claimed function of element (f) is "*changing* the proposed profile along the ordinate so that the profile cumulative value is made equal to the target cumulative value." Fresenius, on the other hand, contends

²⁶Fresenius also states that this element is met because the CMS08 includes a microprocessor that causes the A2008 to operate according to the changed profile and achieve the entered target cumulative UF volume removal during the dialysis period. *See* McClenahan Decl. at Ex. 1 (CMS08 System Handbook at F330318, F330327); *see also* Ward Decl. at ¶ 49.

that the Court should construe element (e) so that the claimed function is "*displaying* both the profile cumulative value and the target cumulative value for comparison" and construe element (f) so that the claimed function is "*allowing changing* the proposed profile along the ordinate so that the profile cumulative value is made equal to the target cumulative value." As to the second step of the analysis, both parties agree that the claimed structure is a microprocessor.

The Court does not find Fresenius' proposed construction of the claim to be persuasive or correct. Fresenius' argument is premised on its contention that Appendix G of the specification "makes clear that the user of the claimed invention does the 'comparing' and the user does the 'changing.'" Fresenius Suppl. Brief at 3. What is fatal to Fresenius' position, however, is the fact that it is no longer asking the Court to construe the function of element (e) as "comparing," it is asking the Court to construe element (e) as "*displaying*." Yet, Fresenius has not identified a corresponding *structure* that "displays."²⁷ To the contrary, Fresenius still insists that the claimed structure is a microprocessor. But *neither* a microprocessor *nor* a human/user "displays."

Further, Fresenius focuses only on Appendix G as supporting its proposed construction, but utterly fails to address or refute Baxter's assertion that Appendices F *and* G both disclose a microprocessor that is able to *compare* the target and cumulative values and subsequently *change* the proposed profile along the ordinate. *See* 476:644:45 (Appendix F); 476:677-78 (Appendix G). As such, Baxter has effectively shown that its proposed construction is not at odds with the preferred embodiment in the specification, as Fresenius contends.

Additionally, as Baxter points out in its Supplemental Brief, Fresenius' reliance on *Innovad Inc. v. Microsoft Corp.*, 260 F.3d 1326, 1331 (Fed. Cir. 2001) and *Smith Industries Medical Systems, Inc. v. Vital Signs, Inc.*, 183 F.3d 1347, 1358-59 (Fed. Cir. 1999) is misplaced. The focus of *Innovad* was whether the district court confused two different components of a claimed system, *i.e.* the dialer unit and

²⁷Indeed, while Fresenius also urges the Court in its Supplemental Brief to "expand upon the parties' proposed construction of the structure . . . by including in its construction what the microprocessor does," Fresenius relies on cases that discuss microprocessors programmed to carry out a *specific algorithm*. *See WMS Gaming, Inc. v. Int'l Game Tech.*, 184 F.3d 1339, 1349 (Fed. Cir. 1999); *Tehrani v. Hamilton Med., Inc.*, 331 F.3d 1355, 1362 (Fed. Cir. 2003). Fresenius fails to explain to the Court how these cases relate to the instant case, and cites only to Appendix G of the specification, which does not disclose a specific algorithm.

1 the programming means. *Innovad*, 260 F.3d at 1331. In distinguishing the two, the Federal Circuit
2 noted that the "programming means" disclosed in that particular patent specification included a keypad.
3 *Id.* The Federal Circuit further stated that the keypad "allow[ed] the user to enter telephone numbers."
4 *Id.* at 1329. Fresenius also argues that the Federal Circuit recognized in *Smiths* the "necessity of user
5 involvement" when it acknowledged that "the specification taught 'a flexible bag that can be squeezed
6 to provide pressure for forcing air to the patient.'" *See* Fresenius Supp. Brief at 4 (quoting *Smiths*, 183
7 F.3d at 1358).

8 Baxter does not dispute, however, that some of the claimed structures in the '476 Patent may
9 allow interaction with a user. In fact, elements (b)-(d) and (g) of claim 7 claim allow interaction with
10 a user because the structure includes both the microprocessor *and* the user interface. Indeed, elements
11 (b)-(d) and (g) are similar to the "programming means" discussed in *Innovad* because the claimed
12 functions relate to a user "entering" information. *See Innovad*, 260 F.3d at 1329 (stating that the keypad
13 allows the user to *enter* telephone numbers). In contrast, elements (e) and (f) do not require *entering*
14 and neither party contends that the claimed structure includes a user interface. What Baxter *does* argue
15 – and correctly so – is that Fresenius may not argue that the claimed structure for performing the
16 claimed function (*i.e.* "comparing" or "changing") is a microprocessor and then attempt to substitute the
17 *user* for the microprocessor. This general principle is firmly rooted in the holding of *Davies v. United*
18 *States*, 31 Fed.Cl. 769, 778-79 (1994) ("Patent claims do not cover structures in which a human being
19 *substitutes* for a part of the claimed structure") (emphasis added). Accordingly, since Fresenius admits
20 that the microprocessor of the CMS08/A2008D System does not "compare" the profile cumulative value
21 with the target cumulative value, element (e) is not met and Fresenius has not established that it is
22 entitled to summary judgment on claim 7 of the '476 Patent.

23 3. Claim 5 of the '476 Patent

24 a. Indefiniteness

25 As a second part of its summary judgment motion pertaining to the '476 Patent, Fresenius also
26 argues that the language of claim 5 is either indefinite or non-enabling in violation of 35 U.S.C. § 112.
27 Specifically, Fresenius contends that the claim language: "enable the machine to produce dialysate
28 having particular ultrafiltration characteristics at various times during use of the machine for a dialysis

1 procedure"²⁸ has no plain meaning and would not be understood by one of ordinary skill in the art in
2 light of the specification.²⁹

3 Fresenius bears the burden of proving that claim 5 is indefinite by clear and convincing evidence.
4 *Northern Amer. Vaccine, Inc. v. American Cyanamid Co.*, 7 F.3d 1571, 1580 (Fed. Cir. 1993). The
5 standard for assessing whether a claim is indefinite is whether "one skilled in the art would understand
6 the bounds of the claim when read in light of the specification." *Exxon Research*, 265 F.3d at 1375.
7 Since a patent is presumed to be valid, a claim is not indefinite if it merely "poses a difficult question
8 of claim construction . . . on which expert witnesses . . . disagree." *Id.*; *see also Northern Amer.*
9 *Vaccine, Inc.*, 7 F.3d at 1580. "When claims are amenable to more than one construction, they should
10 be interpreted so as to preserve their validity." *Modine Mfg. Co. v. United States Int'l Trade Comm'n*,
11 75 F.3d 1545, 1557 (Fed.Cir.1996), abrogated on other grounds, *Festo Corp. v. Shoketsu Kinzoku Kogyo*
12 *Kabushiki Co., Ltd.*, 234 F.3d 558 (Fed.Cir.2000) (en banc). Only "[i]f a claim is insolubly ambiguous,
13 and no narrowing construction can be properly adopted . . . [is] the claim indefinite." *Exxon Research*,
14 265 F.3d at 1375.

15 In support of its argument that the preamble to claim 5 is indefinite, Fresenius relies on the
16 testimony of its expert, Dr. Ward.³⁰ Dr. Ward has stated:

17
18 ²⁸Claim 5 recites:

19 A method of providing operational instructions to a dialysate-producing
20 machine having a memory and a capability of ultrafiltrating fluid from a patient
21 according to a time-variable ultrafiltration profile, so as to **enable the machine**
22 **to produce dialysate having particular ultrafiltration characteristics at**
23 **various times during use of the machine for a dialysis procedure**, the
24 method comprising . . .

25 476.5 (emphasis added)

26 ²⁹The parties agree that a person of ordinary skill in the art is an engineer, such as a bioengineer
27 or an electrical engineer, with a Bachelor of Science degree or equivalent experience, having at least
28 three years of experience designing medical instruments and access to skilled medical personnel familiar
with hemodialysis.

³⁰Dr. Richard Ward is a tenured Professor of Medicine, in the Division of Nephrology, at the
University of Louisville School of Medicine in Louisville, Kentucky. Ward Decl. at ¶ 5. He is a bio-
engineer with over thirty years experience in researching, teaching, and writing about the various
technical aspects of hemodialysis. *Id.*

1 The claim language 'enable the machine to produce dialysate having particular
2 ultrafiltration characteristics at various times during use of the machine for a
3 dialysis procedure' would not be understood by one of ordinary skill in the art.
4 In addition, I find nothing in the patent's written description explaining this
5 phrase or suggesting that the named inventors gave it a special meaning.
6 Finally despite my years of experience in the hemodialysis field, I have not
7 heard such an expression used, nor do I understand the meaning of this claim
8 language. Dialysate does not have 'ultrafiltration characteristics.'

9 Ward Decl. at ¶ 30.³¹

10 To further elucidate the basis for his opinion, Dr. Ward provides the following explanation with
11 regard to the way that ultrafiltration operates:

12 The process of ultrafiltration in hemodialysis relies upon a pressure gradient,
13 typically created by reducing the pressure on the dialysate side of the
14 semipermeable membrane of the dialyzer. The rate of ultrafiltration is
15 controlled by the rate at which the UF pump removes ultrafiltrate from the
16 closed system, and does not depend on the composition of the dialysate. When
17 the UF pump removes fluid from the closed system on the dialysate side of the
18 membrane, the pressure in the dialysate compartment is reduced. That
19 reduction in pressure creates a pressure difference between the blood and
20 dialysate which causes fluid to move from the blood to the dialysate. To
21 preserve the volume of the closed system, the rate of fluid movement from the
22 blood to the dialysate must match the rate at which the UF pump is removing
23 fluid; that is, the ultrafiltration rate. The pressure in the dialysate compartment
24 will adjust to whatever value is necessary to match these two flow rates. For
25 a given ultrafiltration rate, the absolute pressure in the dialysate compartment
26 will be a function of the pressure on the blood side of the membrane and the
27 water permeability of the membrane. In other words, there is no simple
28 relationship between ultrafiltration rate and the pressure in the dialysate
compartment of the dialyzer. Again, the rate of removal of ultrafiltrate is only
controlled by the rate at which the UF pump removes ultrafiltrate from the
closed loop, and this has absolutely nothing to do with how the dialysate is
prepared.

19 *Id.*

20 To refute Dr. Ward's opinion that claim 5 is indefinite, however, Baxter relies on the testimony
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³¹As Baxter notes, Dr. Ward does not appear to have interpreted the disputed phrase in the context of the claim or the specification.

1 of two of its own experts, Dr. Ferraro³² and Dr. Henderson.³³ Dr. Ferraro has stated that "the preamble
 2 to claim 5 would be understood by one of ordinary skill in the art" when read in the context of the claim
 3 and the specification if one construes the term "ultrafiltration characteristics" as meaning "the pressure
 4 at which the dialysate travels through the dialysate compartment of the dialyzer." Ferraro Decl. at ¶ 28.
 5 Dr. Henderson also states that a person of ordinary skill in the art would understand that the term
 6 "dialysate having particular ultrafiltration characteristics" means that the dialysate has "a desired
 7 pressure (characteristic) to create a desired ultrafiltration rate through the dialyzer membrane."
 8 McClenahan Decl. at Ex. 31 (Henderson Expert Report at ¶ 64).

9 Dr. Henderson further elaborated on the proper construction of the disputed phrase in his
 10 deposition. Although admitting that the phrase "dialysate having particular ultrafiltration
 11 characteristics" is not a commonly used phrase in the hemodialysis field and not "the best – the most
 12 clearly stated way" to describe what is being claimed by the patent, he did state that "it's quite apparent
 13 to me what they are getting at here in terms of ultrafiltration characteristics," is that which "relates
 14 through pressure gradients to the amount of ultrafiltration occurring." *Id.* at Ex. 34 (Henderson Depo.
 15 at 135:18-136:13. Specifically, he testified:

16 Q: And I think your testimony is that that phrase refers to the pressure
 17 gradient . . .

18 A: The desired pressure characteristics, in brackets, to create a desired
 19 ultrafiltration rate through the dialyzer machine — desired pressure
 20 characteristic with a characteristic in brackets to create a desired
 21 ultrafiltration rate through the dialyzer membrane.

22 Q: What is the pressure characteristic of the dialysate?

23 A: The gradient.

24 ³²Dr. Richard Ferraro is a staff member at the University of Washington and a senior scientist
 25 at the Institute of Applied Physiology and Medicine. Ferraro Decl. at ¶ 4. He has a Master's Degree
 in Electrical Engineering from the University of Washington and has over thirty years experience as an
 electrical engineer. *Id.* at ¶ 3.

26 ³³Dr. Lee Henderson has a Bachelor of Science Degree from Harvard University and graduated
 27 from the University of Pennsylvania's Medical School in 1957. Henderson Decl. at ¶ 6. He served on
 the faculty of University of Pennsylvania from 1963 to 1974 and, during that time, was the director of
 the Dialysis Unit. *Id.* He also served as the Vice President of Scientific Affairs at Baxter from 1988
 28 to 2000 and as the Vice President Renal Division and Chief Medical Officer of Baxter in 2004. *Id.* at
 ¶ 5. He has authored and co-authored a number of book chapters and articles on nephrology. *Id.* at ¶
 6. He has also edited a book on hemofiltration. *Id.*

1 Q: The gradient across the membrane?

2 A: Yeah.

3 ...

4 Q: Is the desired pressure a property of the dialysate?

5 A: I'm going to say yes, clearly, it is. Dialysate pressure, if you did not
6 have dialysate, you would not have pressure.

7 Q: How do you produce dialysates that have different transmembrane
8 pressures?

9 A: By the pumping system as described here that controls dialysate
10 pressure.

11 *Id.* at Ex. 34 (Henderson Depo. at 136:14-137:19).

12 Dr. Henderson also testified:

13 A: I have read [the phrase producing dialysate] in the context of the
14 [preamble to claim 5]. As one reads this paragraph, it's clear what's
15 being said in terms of the dialysis having a pressure that permits flow
16 of ultrafiltrate.

17 Q: What causes that pressure that permits flow of ultrafiltrate?

18 A: Blood pressure on one side and pressure on the dialysate side.

19 Q: What controls –

20 A: Gradient.

21 *Id.* at Ex. 34 (Henderson Depo. at 138:2-11).

22 Additionally, when Fresenius questioned Dr. Henderson as to whether he was construing the
23 claim in a manner that requires a certain "composition" of dialysate, Dr. Henderson explained that the
24 context of the paragraph, when read in its entirety, makes clear that the "characteristic" that is being
25 referred to is the "pressure gradient" *not* the "dialysate composition":

26 Q: How would I prepare the actual dialysate?

27 A: You don't, but you are taking this out of context. The context relates to
28 dialysate pressure. That's the characteristic, and it isn't the composition
of the dialysate per se. On the other hand, taken in context, in the
paragraph as written, it's quite clear that what's being addressed here is
the pressure and the transmembrane pressure in particular.

...

Q: And you don't understand the phrase, 'to enable the machine to produce
dialysate having particular ultrafiltration characteristics' . . .
To be speaking about the composition of the dialysate, is that correct?

1 A: That's correct.

2 *Id.* at Ex. 34 (Henderson Depo. at 141:22-142:6, 143:2-8).

3 Dr. Henderson reiterated these same opinions in his expert report:

4 In the context of Claim 5, a person of ordinary skill in the art would understand
5 that 'dialysate having particular ultrafiltration characteristics' describes the
6 dialysate having a desired pressure (characteristic) to create a desired
7 ultrafiltration rate through the dialyzer membrane. The claimed time-variable
8 profile controls how quickly the UF pump is stroked. How quickly the UF
pump is stroked controls the pressure on the dialysate side of the dialyzer. The
pressure of the dialysate side of the dialysate controls the rate at which
ultrafiltrate is pulled from inside the membrane to drain. (434:7:35-59).³⁴ This
would be clear to one of ordinary skill in the art.

9 *Id.* at Ex. 31 (Henderson Expert Report at ¶ 64). Importantly, Dr. Henderson also refers to the portion
10 of the specification that teaches the ultrafiltration process. *See* 476:7:35-59. This portion of the
11 specification notes that "[t]he decreased *dialysate pressure* causes a volume of liquid to be removed
12 from the patient that is equal to the volume of liquid removed." *Id.* (emphasis added).

13 Thus, contrary to Fresenius' assertion, the testimony of Dr. Henderson and Dr. Ferraro is not in
14 conflict with Dr. Ward's testimony.³⁵ In fact, the only "conflict" that exists is one created by Fresenius,
15 who has proposed a construction of the disputed phrase – *i.e.* that the term "dialysate having particular
16 ultrafiltration characteristics" means "dialysate having a certain composition" – that is untenable because
17 it is virtually meaningless in the given context. Fresenius has not, however, produced any evidence that
18 a person of ordinary skill in the art would construe the disputed phrase in that manner when reading the
19 patent claim.³⁶ Baxter, on the other hand, has produced testimony from two experts, both undisputedly
20 skilled in the art, who have opined that the language in claim 5 clearly refers to "dialysate having the
21 desired pressure (characteristic)." Accordingly, Fresenius has not met its heavy burden of producing
22

23 ³⁴The Court notes that, due to a typographical error, Dr. Henderson cites to the '434 Patent in his
24 report. The correct citation appears to be 476:7:35-59. The cited language from the two patent
specifications is identical, however.

25 ³⁵Nor are Baxter's experts in conflict with each other. Indeed, the only conflict that Fresenius
26 has identified is the fact that Dr. Henderson stated, during his deposition: "the phrase 'pressure travels'
27 doesn't strike me as a useful one or a knowledgeable one." McClenahan Decl. at Ex. 31 (Henderson
Depo. at 146:21-147:3). However, when the transcript is read in full, it is clear that Dr. Henderson is
merely stating that he did not understand what was meant by the particular deposition question.

28 ³⁶Dr. Ward's testimony does not provide such evidence because Dr. Ward has merely stated that
he does not understand the term "ultrafiltration characteristics."

1 clear and convincing evidence that the patent claim is indefinite. Specifically, Fresenius has not shown
 2 that the claim is "insolubly ambiguous" and that "no narrowing construction can be properly adopted."
 3 *Exxon Research*, 265 F.3d at 1375. Moreover, even if this were a close question, the Federal Circuit
 4 has instructed that "close questions of indefiniteness are properly resolved in favor of the patentee."
 5 *Exxon Research*, 265 F.3d at 1380. Accordingly, the Court hereby DENIES summary judgment on
 6 Fresenius' affirmative defense of indefiniteness as to claim 5 of the '476 Patent.

7 As to Fresenius' affirmative defense of non-enablement, the Court also DENIES summary
 8 judgment. In fact, Fresenius' non-enablement defense rests solely on its ability to prove indefiniteness.
 9 For example, the entirety of Fresenius' discussion pertaining to enablement consists of the following
 10 conclusory sentence: "Thus, even if the term could be found to be definite, and it cannot, the patent
 11 provides no disclosure, let alone enabling disclosure, as to how dialysate with the claimed 'ultrafiltration
 12 characteristics' could be prepared by one of skill in the art." Mot. at 9:4-7.³⁷ Not only is this sentence
 13 incorrect – as Baxter's expert has, in fact, identified the applicable disclosure – but it is completely
 14 unsupported by any citation to the factual record. Further, in complete disregard of its evidentiary
 15 burden, Fresenius improperly urges the Court to grant summary judgment in its favor because *Baxter*
 16 has failed to provide evidence that the patent is enabling. The law is clear, however, that it is not Baxter
 17 who has to make this showing, it is Fresenius.

18 Further, Fresenius' Motion is completely devoid of any discussion of the pertinent *Wand*
 19 enablement factors, such as (1) the quantity of experimentation necessary to make or use the claimed
 20 invention; (2) the amount of direction or guidance presented in the patent; (3) the presence or absence
 21 of working examples in the patent; (4) the nature of the invention; (5) the state of the prior art; (6) the
 22 relative skill of those in the art; (7) the predictability or unpredictability of the art; or (8) the breadth of
 23 the claims. *In re Wands*, 858 F.2d 731. As such, Fresenius has utterly failed in its burden of proof with
 24 regard to enablement.

25 **b. Obviousness**

26
 27 ³⁷Similarly, in the Reply brief, Fresenius states: "And a patent specification which provides no
 28 explanation for the nonsensical claim does not meet the enablement requirement because the claimed
 invention cannot be practiced by one skilled in the art, period, let alone without undue experimentation."
 Reply at 4:13-17.

Fresenius alternatively argues that – if the Court finds that claim 5 is not indefinite or non-enabling – then claim 5 is rendered obvious by a combination of the CMS08/A2008D System and the Sarns System because "a person of ordinary skill in the art would have been motivated to combine the teachings of hemodialysis machines such as the CMS08/A2008D with those of an extracorporeal blood treatment device like the Sarns System." Fresenius is not entitled to summary judgment on this issue for three reasons. First, in its Motion, Fresenius improperly relies solely on the findings of a patent examiner with respect to *related* patent applications to prove its case. As set forth in the separate Order addressing Fresenius' Motion for Summary Judgment on the '434 and '131 Patents, a patent examiner's findings alone are insufficient to merit summary judgment on the issue of validity. *S3, Inc.*, 1999 U.S. Dist. LEXIS 23218 at *86-87 (N.D. Cal. 1999). A district court must review a patent's validity independently of the patent examiner. *Id.*; *see also Quad Env. Technologies Corp. v. Union Sanitary District*, 946 F.2d 870, 876 (Fed. Cir. 1991).

Second, this Court has already found that there are numerous disputed facts pertaining to the issue of the touch screen claims and obviousness, such as, *inter alia*, whether the Sarns System is "analogous art." As Baxter correctly notes, there is also a dispute of fact pertaining to whether the Sarns 9000 roller pumps are precise enough to prepare dialysate. *See Bruner Decl.* at ¶¶ 19-27 (opining that the pumps on the Sarns 9000 are not capable of performing hemodialysis functions); *see Riley Decl.* at ¶ 6 (stating that "[a]ny of the five roller pumps on the Sarns 9000 is capable of delivering dialysate to a hemodialyzer").

Third, to the extent that Fresenius is relying on the Sarns System to meet element (d) of claim 5, Fresenius has not met its burden. Claim 5(d) requires:

- (d) using the touch screen, displaying on the touch screen first and second intersecting axes defining a ultrafiltration profile region, the first axis corresponding to ultrafiltration rate, and the second axis corresponding to time[.]

476.5. Fresenius argues that the Sarns System "has a display screen with a touch screen overlay operable to display first and second intersecting axes defining a time-variable pulsatile profile region, the first axis corresponding to the speed of the pump, represented as a percentage of the user-set speed, and the second axis corresponding to time." *Mot.* at 11:6-11. However, as Baxter points out, this

particular claim element pertains to an *ultrafiltration* profile region, not a "pulsatile profile region." Thus, Fresenius' arguments regarding the Sarns' Pulsatile Screen are irrelevant. Nevertheless, since Fresenius also argues that the CMS08 System displays "first and second intersecting axes defining a graph, with the first axis corresponding to the ultrafiltration rate, and the second axis corresponding to time," its arguments pertaining to the Sarns System are not fatal. Regardless, however, the numerous factual disputes relevant to the obviousness analysis still negate a finding that summary judgment is appropriate.

Accordingly, the Court DENIES Fresenius' Motion with respect to the obviousness of claim 5. This issue shall be decided by the trier of fact.

B. The '027 Patent

As the next part of its Motion for Summary Judgment, Fresenius argues that the asserted claims of the '027 Patent are invalid because claims 1, 2, 4, 6-8, 10, and 12-16 are anticipated by the Seratron System and because claim 11 is rendered obvious by a combination of the Seratron System and the Sarns System.

1. The Status of the Prior Art

a. The Seratron System

Again, before the Court can analyze Fresenius' anticipation and obviousness defenses pertaining to the asserted claims of the '027 Patent, the Court must first address whether the Seratron System – which Fresenius contends includes the Seratron Dialysis System ("Seratron Machine"), the Seratron Modeling Programmer ("Modeling Programmer Machine"), and the Seratron Patient Recording and System Monitoring System ("PRSM") – is properly considered prior art. In support of its Motion for Summary Judgment, Fresenius asserts that the Seratron System was commercially available in the United States and described in printed publications as early as 1981 and thus has priority to the '027 Patent.³⁸ In its Opposition, Baxter alleges that Fresenius has not shown, by clear and convincing evidence, that the entire Seratron System is prior art because: (1) the Modeling Programmer Manual is undated and Fresenius has offered no evidence that it was ever publicly disseminated; (2) the Modeling

³⁸On its face, the '027 patent claims priority to its grandparent application Ser. No. 07/688,174, filed April 19, 1991. For the purposes of this Motion, it will be assumed that the critical date is April 19, 1990. *See* 35 U.S.C. § 102(b).

1 Programmer Machine that Fresenius and Mr. Ragsdale rely on is not the same machine that the
 2 Modeling Programmer Manual describes;³⁹(3) the date of manufacture of the Modeling Programmer
 3 Machine is unclear; (4) the PRSM specification fails to identify any publication date, corporate logo or
 4 identifier, or indicate that it was ever publicly available; and (5) a single witness' uncorroborated
 5 testimony does not suffice as clear and convincing evidence that the PRSM was ever in public use or
 6 sold in the United States.

7 Fresenius, on the other hand, argues that there is a considerable amount of circumstantial
 8 evidence proving that the Seratron Dialysis Control System was commercially available and in public
 9 use in the United States before April 19, 1990. First, Fresenius points out that Mr. Ragsdale⁴⁰ has stated
 10 that the Seratron Dialysis Control System was sold as early as 1981. *See* Ragsdale Decl. at ¶ 7.
 11 Fresenius also points out that Dr. Lipps testified that "Seratronics ceased manufacturing the Seratron,
 12 and had no sales of Seratrons, at sometime after 1983, but in any event no later than 1985." Abernathy
 13 Decl. at Ex. 11 (Lipps Depo. at 10:25-11:2, 13:2-9). To corroborate this testimony, Fresenius notes that
 14 the Seratron Dialysis Control System Manual is dated 1979. *See* McClanahan Decl. at Ex. 16.
 15 Fresenius also notes that the Seratron Dialysis Control System Technician's Manual bears the date of
 16 August 27, 1982. Zheng Decl. at Ex. F.

17 While Fresenius' evidence may corroborate the public use of the Seratron Dialysis System,
 18 Fresenius' corroborating evidence does not extend to the Modeling Programmer Machine. With respect
 19 to this part of the allegedly invalidating prior art reference, Fresenius relies only on the fact that Dr.
 20 Ward has stated that the Modeling Programmer was introduced by Seratronics in the early 1980's. Ward
 21 Decl. at ¶ 24. Fresenius also relies on the testimony of Mr. Ragsdale, who has testified that he
 22 personally saw patients undergoing treatment on a Seratron System, with the Modeling Programmer,
 23 "many times" in the early 1980's. *See* Zheng Decl. at Ex. G (Ragsdale Depo. at 76:25-77:5, 78:1-13).
 24 Without introducing independent corroborating evidence of this fact, however, Fresenius has not carried

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 26 ³⁹Specifically, Baxter asserts that the Modeling Programmer Machine that Baxter inspected and
 27 that Mr. Ragsdale operated when forming his opinion has seven extra buttons on it, indicating that it is
 a different version of the machine.

28 ⁴⁰Mr. Ragsdale was employed as the Manager of Research Electronics by Cordis Dow
 Corporation from May 1979 to June 1982 and then by Seratronics from June 1982 to May 1983. *Id.* at
 ¶ 6.

1 its burden of proof on the instant summary judgment motion. "The law has long looked with disfavor
2 upon invalidating patents on the basis of mere testimonial evidence absent other evidence that
3 corroborates that testimony." *Finnigan Corp. v. Int'l Trade Comm'n*, 180 F.3d 1354, 1366 (Fed. Cir.
4 1999). "[T]he need for corroboration exists regardless of whether the party testifying concerning the
5 invalidating activity is interested in the outcome of the litigation . . . or is uninterested but testifying on
6 behalf of an interested party." *Id.* at 1367. As stated by the Federal Circuit in *Juicy Whip, Inc. v.*
7 *Orange Bang, Inc.*, 292 Fed. 728, 743 (Fed. Cir. 2002), "Reliable evidence of corroboration preferably
8 comes in the form of physical records that were made contemporaneously with the alleged prior
9 invention." *Id.*

10 Here, however, the evidence pertaining to the Modeling Programmer Machine is unclear. For
11 example, as Baxter points out, the Modeling Programmer Manual is undated and Fresenius has offered
12 no "physical" evidence, at this juncture, that it was ever publicly disseminated. Moreover, given that
13 there appears to be two versions of the Modeling Programmer Machine, the resolution of which
14 Modeling Programmer Machine should be used for the prior art determination involves factual
15 determinations that cannot be resolved on summary judgment.

16 Similarly, the "public use" of the PRSM is uncorroborated and, thus, not established. Although
17 Fresenius contends that the PRSM was in public use before 1990, Fresenius relies solely on the
18 deposition testimony of Mr. Ragsdale, who stated that he personally installed the Seratron System with
19 the PRSM system at a clinic in Orange County, and "saw patients on Seratron." *See Zeng Decl.* at Ex.
20 G (Ragsdale Depo. at 77:16-78:5). Notably, although Fresenius states that "there is plenty of
21 circumstantial documentary evidence to corroborate Mr. Ragsdale's testimony," Fresenius does not
22 identify any of it in its brief. *See Reply* at 13:6-8.⁴¹

23 Overall, the Court does not find that Fresenius has proven that it has met its heavy evidentiary
24 burden and is entitled to summary judgment on this issue, particularly since the facts must be viewed
25 in the light most favorable to Baxter. *T.W. Elec. Serv.*, 809 F.2d at 631. Moreover, a prior art
26 determination depends on underlying questions of fact. *Northern Telecom, Inc. v. Datapoint Corp.*, 908

27
28 ⁴¹Although Fresenius argues that it need not establish whether the PRSM is prior art in order to
prove the invalidity of claims 4 and 6 of the '027 Patent, since there are factual issues pertaining to the
Modeling Programmer Machine, summary judgment is still not appropriate.

F.2d 931, 936 (Fed. Cir. 1990). Here, there are numerous issues of fact that have not been sufficiently resolved by Fresenius in its briefing. Accordingly, summary judgment on the '027 Patent is DENIED. Nevertheless, for the sake of clarity and judicial efficiency, the Court's analysis of the parties' specific invalidity arguments are set forth below.

2. Construction of the phrase "Reflecting/Concerning a Particular Selection of Dialysate"

The parties agree that the validity of most of the asserted claims of the '027 Patent hinges on the construction of the claim term "data reflecting/concerning a particular selection of dialysate to be circulated," which appears in claims 1 and 7. As such, the Court must construe this disputed claim term.

Claim 1 recites:

A kidney dialysis machine comprising:

- (a) means for circulating dialysate at a dialysate conductivity through a dialysate circuit including a dialysate compartment for a dialyzer;
- (b) means for circulating blood from a dialysis patient through an extracorporeal blood circuit including a blood compartment of the dialyzer; and
- (c) control means operable to receive chemical-composition **data reflecting a particular selection of dialysate to be circulated** and to calculate from the data an expected conductivity reading of the dialysate and to automatically set conductivity alarm limits around the expected conductivity reading.

027.1 (emphasis added).

Claim 7 recites:

7. A kidney dialysis machine, comprising:

- (a) a dialysate pump for circulating dialysate at a dialysate conductivity through a dialysate circuit including a dialysate compartment for a dialyzer; and
- (b) a controller operable to receive non-conductivity **data concerning a particular selection of dialysate to be circulated** and to calculate from the data an expected conductivity reading of the dialysate.

027.7 (emphasis added).

Fresenius contends that the phrase "data reflecting/concerning a particular selection of dialysate to be circulated" should be given its plain and ordinary meaning. Baxter contends, however, that the

1 phrase "particular selection of dialysate" means: "brand of dialysate concentrate." The Court hereby
2 rejects Baxter's narrow construction and finds that the phrase shall be given its plain and ordinary
3 meaning.

4 Baxter first argues that its construction is correct because "the specification and prosecution
5 history of the '027 Patent establish that the microprocessor of Claims 1 and 7 receives data reflecting
6 the particular selection of brand of dialysate concentrate in order to calculate the expected conductivity."
7 Baxter is correct that the specification refers to the dialysate "brand." For example, the specification
8 provides:

9 The software controlling the operation of the machine's microprocessor
10 includes a routine for predicting correct dialysate conductivity. Such
11 predictions automatically reflect *the particular brand of concentrate* being
12 used, since different groups of concentrate brands require different
13 proportioning to yield a dialysate having a correct ionic strength and
14 electrolytic profile.

15 *See* 027:26:66-27:5 (emphasis added). However, although the Court may examine a specification when
16 construing claims, a court is not allowed to read limitations from the specification into the claims. *See*
17 *Burke, Inc.*, 183 F.3d at 1340. In fact, it is well established that limitations unintended by the patentee
18 cannot be imported from examples, figures, or preferred embodiments. *Phillips v. AWH Corp.*, 415 F.3d
19 1303, 1323 (Fed. Cir. 2005) (en banc). Thus, even where a patent describes only a single embodiment,
20 claims will not be read restrictively unless the patentee has demonstrated a clear intention to limit the
21 claim scope. *Innova/Pure Water, Inc.*, 381 F.3d at 1117 (citing *Liebel-Flarsheim Co. v. Medrad, Inc.*,
22 358 F.3d 898, 906 (Fed Cir. 2004)). Importantly, as Fresenius points out, Baxter has *not* shown that the
23 specification ascribes any special meaning to the phrase "data reflecting/concerning a particular
24 selection of dialysate to be circulated." In fact, the term "a particular selection of dialysate to be
25 circulated" does not appear anywhere in the specification.

26 Baxter's argument that the prosecution history supports its claim construction is also unavailing.
27 For instance, Baxter claims that the prosecution history supports its narrow construction because the
28 examiner requested that the language "reflecting a particular selection of dialysate to be circulated" be
added to the pending claims and cited this amendment in his "Reasons for Allowance." Abernathy Decl.
at Ex. 3. However, there is no indication in the record that the applicants expressly adopted the
examiner's reasons for allowance or agreed that the amendments made by the examiner were made to

1 overcome prior art. "Although prosecution history can be a useful tool for interpreting claim terms, it
2 cannot be used to limit the scope of a claim unless the applicant took a position before the PTO that
3 would lead a competitor to believe that the applicant had disavowed coverage of the relevant subject
4 matter." *Schwing GmbH v. Putzmeister Aktiengesellschaft*, 305 F.3d 1318, 1324 (Fed. Cir. 2002). Here,
5 Baxter has simply not shown that the inventors made a clear disavowal of claim scope during
6 prosecution.

7 It is also significant that Baxter's current claim construction conflicts with the construction
8 offered by Baxter's expert, Dr. Ferraro, on the issue of infringement. For example, in his expert report,
9 Dr. Ferraro opined that "a particular selection of dialysate" could refer to "concentration parameters of
10 the dialysate." *See* McClenahan Decl. at Ex. 32. The law is clear that Baxter cannot assert that one
11 meaning should be ascribed to a claim for the purposes of an infringement analysis and then later
12 contend that another meaning should apply for the purposes of the validity analysis. *See Amazon.com,*
13 *Inc. v. BarnesandNoble.com*, 239 F.3d 1343, 1351 (Fed. Cir. 2001).

14 Accordingly, Fresenius' argument that the disputed phrase should be given its plain and ordinary
15 meaning is persuasive. This construction is in accord with the Federal Circuit's mandate that a court is
16 to indulge a "heavy presumption" that claim terms carry their full ordinary and customary meaning
17 unless the patentee unequivocally imparted a novel meaning to those terms or expressly relinquished
18 claim scope during prosecution. *Omega Engineering, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1323 (Fed.
19 Cir. 2003).

20 3. Anticipation

21 Having concluded that the phrase "data reflecting/concerning a particular selection of dialysate
22 to be circulated" should be given its plain and ordinary meaning, the Court shall next analyze whether
23 the Seratron System anticipates the asserted claims of the '027 Patent. With respect to this defense,
24 Fresenius must prove that the Seratron System embodies **each and every** claim limitation through clear
25 and convincing evidence. *Trinetec Indus., Inc.*, 295 F.3d at 1295-96. In addition to its argument that
26 summary judgment is precluded because there are factual issues pertaining to the prior art, Baxter also
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argues that Fresenius has not met its burden of proof regarding claims 1, 2, 7, 8, 14, 15, and 16.⁴²

a. Claims 1 and 7

With respect to claims 1 and 7, the parties' dispute focuses on whether the Seratron System meets the limitation requiring a "control means operable to receive chemical-composition data reflecting a particular selection of dialysate to be circulated." With respect to claim 1, the parties additionally dispute whether the limitation requiring a control means operable to "automatically set conductivity alarm limits around the expected conductivity reading" is met.

1. "Operable to Receive Chemical-Composition Data Reflecting a Particular Selection Dialysate to be Circulated."

When the phrase "particular selection of dialysate to be circulated" is given its plain and ordinary meaning, Fresenius has convincingly shown that the limitation requiring a "control means operable to receive chemical-composition data reflecting a particular selection of dialysate to be circulated" is met

⁴²Baxter offers no argument regarding claims 4 and 6, which are independent claims. Since Baxter has offered no opposition to the facts laid out in Fresenius' Motion, Fresenius would have been entitled to summary judgment on these claims if it had been able to fulfill its evidentiary burden regarding the prior art. Specifically, Fresenius has shown that there is no dispute that the Seratron System is a kidney dialysis machine with a memory and that the parameters associated with the dialysis treatment in progress, including the total volume of the ultrafiltrate removed, were periodically saved in the MPU RAM, which is the data storage memory on the main motherboard. Fresenius has also shown that it is undisputed that the Seratron System includes a power-fail save system, which protects the data in the RAM, as well as circuitry and software for automatically recalling from the memory, after a pre-selected duration of a power-off condition, the parameters according to which the machine was operating when the power-off occurred. *See* Mot. at 15-16.

There is also no specific argument presented in Baxter's Opposition brief regarding claims 10, 12, and 13; however these claims are dependent on claims 7 and thus the validity arguments regarding claim 7 apply to them. As clear and convincing evidence that claims 10 and 12 are anticipated, Fresenius has shown that there is no dispute that the Modeling Programmer of the Seratron System is a data input device connected to the Seratron Dialysis System controller, and is used by the operator to provide data to the controller. *See* Mot. at 17. Fresenius has also shown that the Seratron System receives non-conductivity data, such as Concentrate Type value, reflecting a particular selection of dialysate, and that this non-conductivity data "concerns" the electrolytic profile of the dialysate resulting from a baseline dilution of the concentrate with water. Additionally, Fresenius has shown that it is undisputed that this information is stored in the Seratron System's memory and used to calculate the expected conductivity of dialysate made using the concentrate. *See id.*

As clear and convincing evidence that claim 13 is anticipated, Fresenius has shown that it is undisputed that "Appendix A to the Modeling Programmer Manual describes the algorithm that is recalled by the Seratron System's controller to calculate the expected conductivity of the dialysate made from the dialysate concentrate." *See id.* at 18.

1 by the Seratron System. Specifically, Fresenius has shown that the Seratron System's microprocessor⁴³
2 receives sodium concentration data reflective of a particular dialysate concentrate selected by the user
3 to be circulated, and calculates from that data an expected conductivity reading. *See* Ragsdale Decl. at
4 ¶¶ 25-30; *see* McClenahan Decl. at Ex. 15 (Seratron Technician's Manual at F006604-7). For example,
5 the Seratron System allows the user to enter the desired baseline sodium concentration, which Fresenius
6 contends is "chemical composition data," either for the entire treatment, or for each of up to seven steps
7 of a sodium profile. *See* McClenahan Decl. at Ex. 12 (Seratron Modeling Programmer Manual at
8 F059484-85). The Seratron System also allows the user to enter a "Concentrate Type." *Id.* at Ex. 12
9 (Seratron Modeling Programmer Manual at F09482). The Seratron System's microprocessor uses this
10 Concentrate Type value to determine the algorithm it will use to calculate the expected conductivity.
11 *Id.* at Ex. 12 (Seratron Modeling Programmer Manual at F059511). Once the user enters a desired
12 baseline sodium concentration value (*i.e.* chemical composition data), the Seratron System, using the
13 algorithm associated with the Concentrate Type value, calculates an expected conductivity value for that
14 baseline sodium concentration value. *Id.* at Ex. 12 (Seratron Modeling Programmer Manual at
15 F059510); Ragsdale Decl. at ¶¶ 27-29. The Modeling Programmer Manual describes the equations used
16 by the Seratron System to calculate expected dialysate conductivity. McClenahan Decl. at Ex. 12
17 (Seratron Modeling Programmer Manual at F059510-59512); Ragsdale Decl. at ¶ 28. Fresenius' expert,
18 Mr. Ragsdale, has opined that the aforementioned functions meet the limitation of claim 1 requiring a
19 "control means operable to receive chemical-composition data reflecting a particular selection of
20 dialysate to be circulated." Ragsdale Decl. at ¶¶ 25-29.

21 Baxter has not offered any expert testimony showing that the Seratron System's microprocessor
22 is not operable to receive "chemical-composition data reflecting a particular selection of dialysate."
23 Instead, Baxter argues that Mr. Ragsdale "conceded," during his deposition, that "almost all concentrates
24 ha[ve] the 'essentially the same parameters.'" *See* Opp. at 10:12-15 (citing Abernathy Decl. at Ex. 1

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26 ⁴³The parties agree that the structure required by this limitation is a microprocessor. *See*
27 Abernathy Decl. at Ex. 4. The parties also do not dispute that the Seratron System meets elements (a)
28 and (b) of claim 1 because the Seratron System is a kidney dialysis machine that has: (a) a means for
circulating dialysate at a dialysate conductivity through a dialysate circuit including a dialysate
compartment for a dialyzer and (b) a means for circulating blood from a dialysis patient through an
extracorporeal blood circuit including a blood compartment of the dialyzer. *See* 027.1.

(Ragsdale Depo. at 75:7-11)). This misstates Mr. Ragsdale's deposition testimony, however. What Mr. Ragsdale actually stated in his deposition is that many brands of dialysate have the same parameters⁴⁴ – which is why it is not necessary to enter brand information – and that the Seratron System recognizes six distinct types of concentrate. *See* Abernathy Decl. at Ex. 1 (Ragsdale Depo. at 75:1-11). Other than unpersuasively arguing that the claim limitation requires recognition of a particular brand, Baxter fails to explain, through any expert testimony, how the fact that the Seratron System needs only six concentrates types is relevant to the analysis or alters the conclusion that the claim limitation is met.

Indeed, the only expert testimony that Baxter has offered is a fairly conclusory statement from Dr. Ferraro that "the sodium concentration provides no information about, and is not reflective of a particular selection of concentrate at all." *See* Ferraro Decl. at ¶ 18. However, again, this conclusion is based on an incorrect construction of the claim. Baxter also relies on the expert report of Dr. Henderson, who states that "sodium concentration data" is not "chemical composition data" because "chemical composition data" refers only to the "chemical makeup of each relevant electrolyte in the brand of concentrate used to prepare the dialysate," and "must be reflective of the entire electrolytic profile of the specific brand of concentrate and its mixing ration use to prepare dialysate." McClenahan Decl. at Ex. 31 (Henderson Expert Report at ¶¶ 81-82). However, as Fresenius points out in its Motion, this construction excludes the preferred embodiment disclosed in the '027 Patent⁴⁵ and therefore must be rejected. *SanDisk Corp.*, 415 F.3d at 1285.

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2. "Operable to . . . Automatically Set Conductivity Alarm Limits Around the Expected Conductivity Reading."

⁴⁴Mr. Ragsdale further explains that the term "parameters" means "electrolytic composition." Abernathy Decl. at Ex. 1 (Ragsdale Depo. at 75:12-15).

⁴⁵For example, the specification expressly teaches that for "all brands of acetate concentrates," the expected conductivity of the dialysate is determined by an algorithm wherein "the operator enters the baseline concentration of sodium[.]" *See* 027:28:10-17.

1 There are factual issues relating to claim 1, however, that preclude summary judgment.⁴⁶ The
2 factual issues pertain to whether the Seratron System teaches the "alarm limits" claim element. This
3 claim element is also found in claims 8 and 16 and thus, in addition to the other reasons set forth in this
4 Memorandum, summary judgment is precluded as to those claims on this basis as well.

5 Relying on the Ragsdale Declaration, Fresenius argues that the Modeling Programmer Manual
6 teaches that the Seratron System automatically sets conductivity alarm limits at 0.5 mMho/cm above
7 and below the expected conductivity value. Ragsdale Decl. at ¶ 30; *see also* McClenahan Decl. at Ex.
8 12 (Seratron Modeling Programmer Manual at F059468) ("The new alarm limits will automatically be
9 established at plus or minus 0.5 mMhos of the new set point."). Fresenius also argues that, if the set
10 point is changed by the user, either directly by using the COND button, or indirectly using the PROG
11 Na+ button, the alarm limits are automatically changed. Ragsdale Decl. at ¶ 30.

12 Baxter has demonstrated, however, that Ragsdale's memory regarding this particular function
13 of the Seratron System is faltering and that his testimony is equivocal. For example, in response to a
14 line of questioning on this issue, Mr. Ragsdale stated: "I would like to confirm — I can't at this moment,
15 but I'm realizing now that we need to test this, or I could dig through the [source] code and look at this."
16 *See* Abernathy Decl. at Ex. 1 (Ragsdale Depo. at 153:6-9). Mr. Ragsdale further stated, "We could fire
17 up the Seratron, enter it, you know, and look at what the programmer does. I believe now — I'm sort of
18 remembering that you can press the conductivity key and you can follow what — you know, what had
19 been calculated." *Id.* at Ex. 1 (Ragsdale Depo. at 153:12-16).⁴⁷ Similarly, Mr. Ragsdale's memory
20 regarding the disclosures in the Technician's Manual was hazy. *Id.* at Ex. 1 (Ragsdale Depo. at 155:1-5)
21 ("I believe the technician manual does have that information in it if you refer to it, but I believe — but
22 I have to sit here and go through the whole thing again to make sure."). Mr. Ragsdale further admitted
23 that there were two different types of the Programmer and that the one he was relying on to form his
24 opinion differed from the one disclosed in the 1979 Operator's Manual. *Id.* at Ex. 1 (Ragsdale Depo.

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26 ⁴⁶Since there are factual issues pertaining to claim 1, summary judgment on claim 2 — which is
27 a dependent claim — is precluded.

28 ⁴⁷While Fresenius is correct that this particular testimony pertains to whether the Seratron
System "displays" certain information, which is not necessarily at issue here, the fact that his
recollection is less than complete opens the door for certain credibility and weight-of-the-evidence
determinations that need to be made by the trier of fact.

1 at 154:5-10).

2 In sum, Mr. Ragsdale's testimony makes clear that the resolution of the validity of claim 1
3 depends on a factual determination that is best left to the trier of fact. *See, e.g., id.* at Ex. 1 (Ragsdale
4 Depo. at 158:12-17) ("During the process I had – I had my hands on a Seratron, and one of things I did
5 that evening was started entering values in the programmer to refresh my memory of how it actually
6 worked. But I'd love to have one here, and we could answer this right like that."). As such, for this
7 additional reason, summary judgment is DENIED.

8 **b. Claims 14, 15, and 16**

9 Baxter also asserts that claims 14, 15, and 16 are not anticipated because the Seratron System
10 does not proportion concentrate with water using a proportioning pump, but rather uses a different
11 mechanism called a "servo control." Yet again, with respect to these claims, there are disputed facts that
12 cannot be resolved on summary judgment.

13 Claims 14, 15, and 16 recite:

- 14 14. The kidney dialysis machine of claim 7, further comprising a
15 proportioning pump for diluting a dialysate concentrate at a
16 proportioning ratio with water to make the dialysate.
17 15. The kidney dialysis machine of claim 14, wherein the proportioning
18 ratio is variable.
19 16. The kidney dialysis machine of claim 15, wherein the controller
20 recalculates the expected dialysate conductivity and sets new
21 conductivity alarm limits around the recalculated expected dialysate
22 conductivity whenever the proportioning ratio is changed.

23 027.14-16. As set forth above, claim 14 is dependent on claim 7 and adds the limitation that the
24 machine uses a "proportioning pump for diluting a dialysate concentrate at a proportioning ratio with
25 water to make the dialysate." 027.14. Claim 15 depends on claim 14 and further adds that the
26 proportioning "ratio is variable." 027:15. Claim 16 depends on Claim 15 and adds that the machine
27 "sets new conductivity alarm limits around the recalculated expected dialysate conductivity whenever
28 the proportioning ratio is changed." 027:16. Thus, the validity of each of these claims depends on
Fresenius' ability to establish that the Seratron System has a "proportioning pump for diluting a dialysate
concentrate at a proportioning ratio."

Fresenius contends that the Seratron System embodies each and every element of claims 14, 15,

1 and 16 because the system includes such a proportioning pump. To support its assertions, Fresenius
 2 relies on the Ragsdale Declaration and excerpts from the Seratron Technician's Manual. *See* Ragsdale
 3 Decl. at ¶ Ex. 15; *see also* McClenahan Decl. at Ex. 15 (F006575-79, F006620-26). Baxter's expert, Dr.
 4 Ferraro, on the other hand, has opined that the claims 14, 15, 16 are not met by the Seratron System
 5 because the Seratron System uses a "servo system" that measures the conductivity of the concentrate-
 6 water mix through a conductivity probe. Ferraro Decl. at ¶ 14. He further explains that a "servo"
 7 system differs from a proportioning pump or system because a proportioning system will always pump
 8 the same ratio, regardless of the amount of ionization in the water.⁴⁸ *Id.* at ¶¶ 14-17. In fact, he
 9 contends that the two types of systems differ significantly because they: (1) operate and function in a
 10 different manner; (2) produce a different output; (3) are constructed from different components; and (4)
 11 have different "pros and cons." *Id.* at ¶ 18. The difference between the two experts' opinions depends
 12 greatly on a factual issue – *i.e.* the manner in which the Seratron System actually functions – that cannot
 13 be reconciled on summary judgment. "Although patent issues are as amenable to summary resolution
 14 as other matters, when material facts are disputed, and testimonial, documentary, and expert evidence
 15 are needed for their resolution, summary adjudication is not indicated." *Quad Environmental*
 16 *Technologies Corp.*, 946 F.2d at 872. Further, as noted above, Baxter had identified certain
 17 equivocations in Mr. Ragsdale's testimony that give rise to credibility determinations best left to the trier
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 22 ⁴⁸Although Fresenius contends that the Court should disregard Dr. Ferraro's expert opinion
 23 because it "contradicts" the evidence, Fresenius supports this assertion only by generally citing to
 24 excerpts from the Seratron Programmer Manual and the Operations Manual. Fresenius does not explain
 25 to the Court how, exactly, Dr. Ferraro's expert opinion is flatly contradicted by this evidence. The
 26 inadequacy of this dismissal of Dr. Ferraro's testimony is underscored by the fact that even Mr. Ragsdale
 27 has admitted that a great deal of his testimony regarding the operation of the Seratron System is not
 28 based on the manuals, but rather on his own implicit knowledge of the way the system works. *See*
 Abernathy Decl. at Ex. 1 (Ragsdale Depo. at 190:2-192:25) ("That means you are changing the pump
 rate and therefore the ration of concentrate mixed with aerated water. So I think it's implicit in this also,
 though I don't see the actual term 'proportioning' in this section."). Similarly, Fresenius' attorney's bare,
 unsupported assertion that "the claim does not require the use of an 'open loop' system," *see* Reply at
 14:1-2, is not persuasive in light of expert testimony from a person skilled in the art who has read the
 same Seratron System references and has explained, in considerable detail, why the claim is not met by
 a closed loop servo control mechanism. *See* Ferraro Decl. at ¶¶ 8-26. This Court cannot simply
 disregard Dr. Ferraro's testimony based on mere attorney advocacy.

1 of fact.⁴⁹ Accordingly, since Fresenius' Motion relies heavily on Mr. Ragsdale's testimony regarding
 2 the function of the proportioning pump, summary judgment is inappropriate.

3 4. Obviousness

4 Finally, Fresenius contends that claim 11 is rendered obvious by a combination of the Seratron
 5 System and the Sarns System because "replacing the membrane switches of the Modeling Programmer
 6 with a touch screen overlay as the input device would have been obvious to one of skill in the art." Mot.
 7 at 20:1-3.

8 For the same reasons set forth above with regard to Fresenius' obviousness defense and claim
 9 5 of the '427 Patent, the Court hereby DENIES Fresenius' Motion for Summary Judgment with respect
 10 to claim 11 of the '027 Patent. Again, Fresenius cannot rely solely on the findings of a patent examiner
 11 to meet its evidentiary burden and there are numerous disputed facts that must be resolved before the
 12 issue of obviousness can be determined, particularly facts pertaining to whether "a person of ordinary
 13 skill in the art would have been motivated to combine the teachings of hemodialysis machines such as
 14 the Seratron System with those of an extracorporeal blood treatment device like the Sarns System," as
 15 Fresenius contends. Accordingly, summary judgment on claim 11 of the '027 Patent is DENIED.

16 CONCLUSION

17 IT IS HEREBY ORDERED THAT Fresenius' Motion for Summary Judgment of Invalidity of
 18 the Asserted Claims of U.S. Patent Nos. 5,326,476 and 5,744,027 [Docket No. 441] is DENIED.

19 IT IS SO ORDERED.

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 21 Dated: 5/24/06

Saundra B. Armstrong
 SAUNDRA BROWN ARMSTRONG
 United States District Judge

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 28 ⁴⁹For example, as noted earlier, Ragsdale stated several times during his deposition that he would
 "have to go back and look at that part of the system," or "would like to reconfirm." Gemmell Decl. at
 Ex. B (Ragsdale Depo. at 139:16-24, 153:6-8, 157:14-20).